



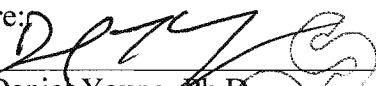
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1 ASSAY BACKGROUND

1.1 Theranos System Specification

Thyroid Stimulating Hormone (TSH) is a glycoprotein hormone which stimulates the thyroid to produce thyroxine (T4) and triiodothyronine (T3) to stimulate metabolism. TSH structure consists of an alpha and beta subunit. The alpha subunit shares homology with FSH, LH and hCG. There is some homology in the beta subunits. TSH activates the thyroid gland to stimulate production and release of thyroxine (T4) and triiodothyronine (T3).

Diagnostic testing for TSH is usually part of a panel to test thyroid function. This information can be used to determine the causes of hypothyroidism (underactive) or hyperthyroidism (overactive), and also track treatment of both conditions. The normal range of TSH in adults is 0.3-5uIU/mL and in children, 0.4-19uIU/mL. Levels of TSH below 0.1uIU/mL are consistent with hyperthyroidism, and levels above 5uIU/mL are consistent with hypothyroidism, however standard medical practice relies on confirmation of abnormal TSH results using additional thyroid tests such as free T4, total T4 and total T3, and should be interpreted in the appropriate clinical context.

1.2 Theranos TSH Assay Specifications

This assay is designed to detect human TSH in human plasma and serum. The assay has a reportable range of 0.1 to 50 uIU/mL, and uses the WHO Third International Standard (NIBSC 81/565) as a reference material. The ULOQ is 50 uIU/mL and LLOQ is 0.1 uIU/mL. The reference interval measured by the assay is 0.4-4 uIU/ml.

1.3 Reference Assay

The IMMULITE 2000 Third Generation TSH assay was used as a predicate method. EDTA plasma is not an acceptable sample type for testing on this platform. The assay reportable range is 0.04uIU/mL to 75uIU/mL. The presence of bilirubin (200mg/L), packed red blood cells (30uL/mL), and triglycerides (5000mg/dL) has no effect on the assay precision.

2 REGULATION AND GUIDANCE

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

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2 CALIBRATION

- 2.1.1 Acceptance criteria: For each run, a minimum of 75% of the back-calculated mean values of the total number of calibration standards in the calibration range should be within $100 \pm 20\%$ ($100 \pm 25\%$ at LLOQ and ULOQ standards) of their nominal values and a minimum of six unique standard concentrations must be within the assay range.
- 2.1.2 Unless otherwise stated, each level was tested in replicates of 3.
- 2.1.3 A point is considered to be “dark count” if it results in less than 150 RLU. All dark count tips are highlighted in red and are excluded from mean and recovery calculations.

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Table 1: Calibration 1 Complete Data (Edison 3.0)

This calibration set was used to calculate the concentrations in the Reference Range (3), Comparability (4), Linearity (5), and Anticoagulant (7) experiments. Calibrator 1 and Calibrator 9 were confirmed with a second set of 3 replicates for higher precision at the LLOQ and ULOQ.

Nominal Value [uIU/mL]	All Tips		Dark Exclusion		Inter-Cartridge		Intra-Cartridge		Concentration			
	Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip-1	Tip-2	Mean	%CV
50.00	200121	192135	200121	192135	196128	3%	197580	18%	OORH	56.52	OORH	OORH
	227963	246101	227963	246101	237032	5%			OORH	OORH		
	144630	174532	144630	174532	159581	13%			38.05	49.18		
50.00	244571	240814	244571	240814	242693	1%	227052	10%	OORH	OORH	OORH	OORH
	212201	246728	212201	246728	229465	11%			OORH	OORH		
	185753	232245	185753	232245	208999	16%			53.78	OORH		
25.00	94065	114457	94065	114457	104261	14%	94621	13%	22.44	28.30	22.59	16%
	92510	102698	92510	102698	97604	7%			22.01	24.85		
	84516	79482	84516	79482	81999	4%			19.86	18.55		
10.00	41902	40473	41902	40473	41188	2%	40150	6%	9.52	9.20	9.13	6%
	38587	42889	38587	42889	40738	7%			8.78	9.74		
	29797	36900	29797	36900	36900					8.40		
5.00	27043	24855	27043	24855	25949	6%	23083	14%	6.23	5.75	5.36	13%
	20700	18949	20700	18949	19825	6%			4.84	4.46		
	23870	23870	DARK	23870	23870					5.53		
2.50	11560	10223	11560	10223	10892	9%	10167	12%	2.81	2.50	2.49	11%
	10619	10050	10619	10050	10335	4%			2.59	2.46		
	7956	10595	7956	10595	9276	20%			1.97	2.59		
1.00	4402	5257	4402	5257	4830	13%	4739	17%	1.10	1.32	1.19	18%
	3240	5109	3240	5109	4175	32%			0.80	1.28		
	5405	5023	5405	5023	5214	5%			1.36	1.26		
0.50	1755	2460	1755	2460	2108	24%	2604	20%	0.39	0.59	0.63	23%
	3224	3072	3224	3072	3148	3%			0.80	0.75		
	2646	2466	2646	2466	2556	5%			0.64	0.59		
0.25	1526	1525	1526	1525	1526	0%	1349	18%	0.33	0.33	0.28	25%
	979	1358	979	1358	1169	23%			0.17	0.28		
	1138	1567	1138	1567	1353	22%			0.22	0.34		
0.10	656	8	656	DARK	656		696	7%	0.08		0.09	13%
	686	746	686	746	716	6%			0.09	0.11		
	Data Lost											
0.10	626	611	626	611	619	2%	793	21%	OORL	OORL	0.12	30%
	733	849	733	849	791	10%			0.10	0.13		
	903	1036	903	1036	970	10%			0.15	0.19		
0.00	273	231	273	231	252	12%	241	26%	OORL	OORL	OORL	OORL
	192	154	192	154	173	16%			OORL	OORL		
	329	267	329	267	298	15%			OORL	OORL		

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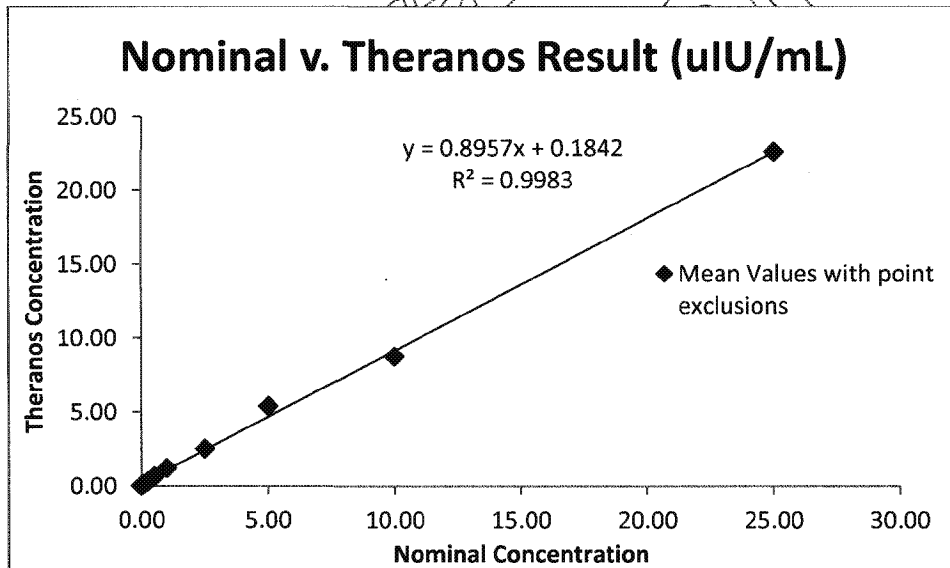
Table 2: Calibration 1 Summary Calculated Concentration

Any individual points that are considered “Dark Counts” were excluded and the mean concentrations at each level were calculated. After the exclusion of all “dark count” data points, the %Recovery is within the acceptable range for all Calibrator Levels.

Calibrator Level	Nominal Value [uIU/mL]	Theranos Result [uIU/mL]	%CV	%Recovery
Calibrator 1	50.00	OORH	OORH	OORH
Calibrator 2	25.00	22.59	16%	90%
Calibrator 3	10.00	9.13	6%	91%
Calibrator 4	5.00	5.36	13%	107%
Calibrator 5	2.50	2.49	41%	100%
Calibrator 6	1.00	1.19	18%	119%
Calibrator 7	0.50	0.63	23%	126%
Calibrator 8	0.25	0.28	25%	110%
Calibrator 9	0.10	0.11	19%	109%
Calibrator 10	0.00	OORL	OORL	OORL

Figure 1: Nominal v. Reported Concentration

This data shows the dark count excluded mean concentration calculations. The 50uIU/mL level is excluded because it is outside of the assay range.



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Table 3: Calibration 2 Complete Data (Edison 3.0)

This calibration set was used to calculate the concentrations in the Blood Collection Device Comparison (6) experiments. Calibrators 9 and 10 were re-tested in replicates of 3 for confirmation.

Nominal Value [uIU/mL]	All Tips		Dark Exclusion		Inter-Cartridge		Intra-Cartridge		Concentration			
	Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip 1	Tip 2	Mean	%CV
50.00	228723	227658	228723	227658	228191	0%	208782	10%	55.63	55.32	49.95	11%
	211073	217373	211073	217373	214223	2%			50.59	52.37		
	188849	179017	188849	179017	183933	4%			44.44	41.79		
25.00	110805	68531	110805		110805		111753	4%	24.41		24.64	5%
	108448	118559	108448	118559	113504	6%			23.84	26.30		
	109198	139	109198	DARK	109198				24.02			
10.00	50106	53073	50106	53073	51590	4%	51251	11%	10.41	11.06	10.66	12%
	44469	45196	44469	45196	44833	1%			9.17	9.33		
	58566	56095	58566	56095	57331	3%			12.28	11.73		
5.00	21473	22821	21473	22821	22147	4%	23430	6%	4.28	4.56	4.69	6%
	24340	24160	24340	24160	24250	1%			4.88	4.84		
	22769	25019	22769	25019	23894	7%			4.55	5.02		
2.50	12906	14798	12906	14798	13852	10%	13032	10%	2.52	2.90	2.54	10%
	6	50	DARK	DARK								
	11818	12604	11818	12604	12211	5%			2.30	2.46		
1.00	4175	4356	4175	4356	4266	3%	5075	13%	0.77	0.80	0.95	14%
	5683	5747	5683	5747	5715	1%			1.07	1.08		
	5116	5370	5116	5370	5243	3%			0.95	1.00		
0.50	2547	2	2547	DARK	2547		2600	9%	0.45		0.46	10%
	2852	2825	2852	2825	2839	1%			0.51	0.51		
	2514	2264	2514	2264	2389	7%			0.45	0.40		
0.25	2044	1563		1563	1563		1506	13%	OORL	0.26	0.25	15%
	1220	1412	1220	1412	1316	10%			0.20	0.23		
	1730	1607	1730	1607	1669	5%			0.29	0.27		
0.10	860	923	860	923	892	5%	672	27%	0.13	0.14	0.09	31%
	657	609	657	609	633	5%			0.09	0.08		
	485	497	485	497	491	2%			OORL	OORL		
0.10	1081	802	1081	802	942	21%	867	21%	0.17	0.12	0.13	27%
	1040	955	1040	955	998	6%			0.16	0.15		
	675	646	675	646	661	3%			0.09	0.09		
0.00	189	200	189	200	195	4%	203	17%	OORL	OORL	OORL	OORL
	194	262	194	262	228	21%			OORL	OORL		
	170	66	170	DARK	170				OORL			
	201	155	201	155	178	18%	205	24%	OORL	OORL	OORL	OORL
	272	192	272	192	232	24%			OORL	OORL		
	5	47	DARK	DARK								

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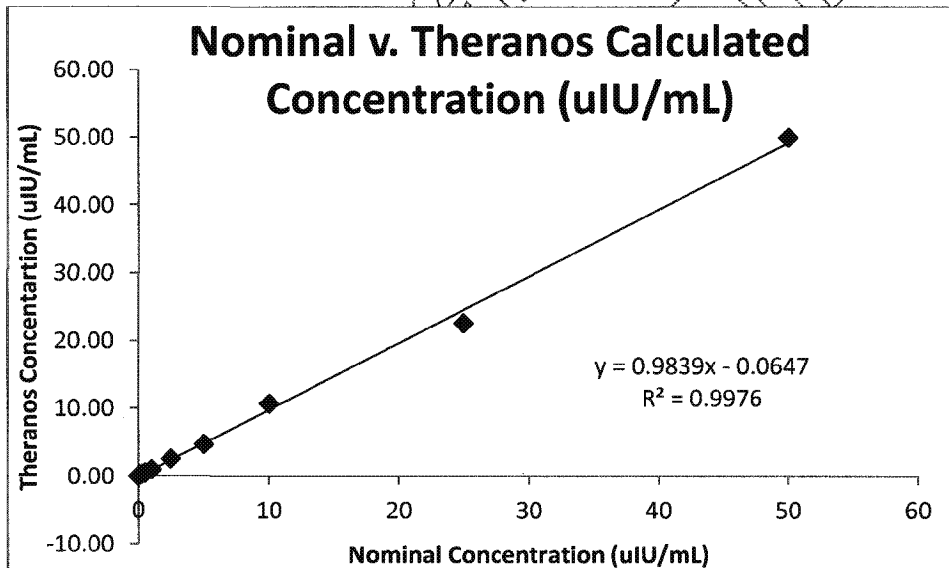
Table 4: Calibration 2 Summary Calculated Concentration

Any individual points that are considered “Dark Counts” were excluded and the mean concentrations at each level were calculated. After the exclusion of all “dark count” data points, the %Recovery is within the acceptable range.

Calibrator Level	Nominal Value [uIU/mL]	Theranos Result [uIU/mL]	%CV	%Recovery
Calibrator 1	50.00	49.95	11%	100%
Calibrator 2	25.00	24.64	5%	99%
Calibrator 3	10.00	10.66	12%	107%
Calibrator 4	5.00	4.89	6%	94%
Calibrator 5	2.50	2.54	10%	102%
Calibrator 6	1.00	0.95	14%	95%
Calibrator 7	0.50	0.46	10%	92%
Calibrator 8	0.25	0.25	15%	101%
Calibrator 9	0.10	0.11	26%	112%
Calibrator 10	0.00	OORL	OORL	OORL

Figure 2: Nominal v. Reported Concentration

This data shows the dark count excluded mean concentration calculations.



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Table 5: Calibration 3 All Data (Edison 3.0)

This calibration set was used to calculate the concentrations in Analytical Sensitivity (8) Interference (9) and Cross-reactivity (10) experiments.

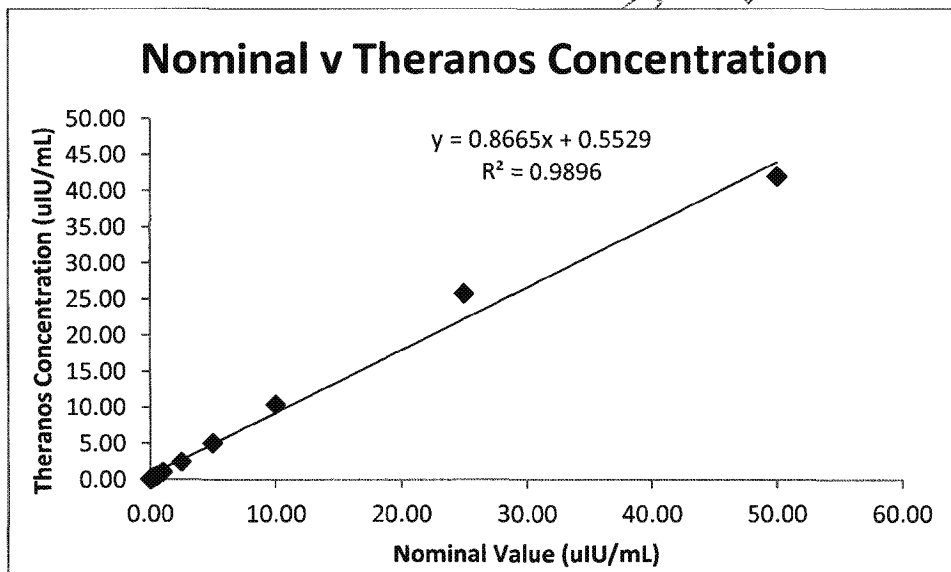
Nominal Value [uIU/mL]	All Tips		Dark Exclusion		Inter-Cartridge		Intra-Cartridge		Concentration			
	Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip 1	Tip 2	Mean	%CV
50.00	139815	156819	139815	156819	148317	8%	189710	19%	28.43	32.73	41.92	26%
	225762	185267	225762	185267	205515	14%			53.60	40.61		
	231986	198608	231986	198608	215297	11%			55.82	44.63		
25.00	97121	129433	97121	129433	113277	20%	128551	19%	18.68	25.93	25.72	23%
	105730	127043	105730	127043	116387	13%			20.54	25.36		
	152051	159929	152051	159929	155990	4%			31.50	33.55		
10.00	59424	57801	59424	57801	58613	2%	55623	9%	11.08	10.77	10.35	9%
	60885	50778	60885	50778	55832	13%			11.36	9.43		
	56535	48315	56535	48315	52425	11%			10.52	8.97		
5.00	25245	24623	25245	24623	24934	2%	26938	12%	4.71	4.60	5.02	12%
	25190	25848	25190	25848	25519	2%			4.70	4.82		
	33221	27501	33221	27501	30361	13%			6.17	5.13		
2.50	15554	16689	15554	16689	16122	5%	13704	20%	2.95	3.15	2.61	19%
	7732	11551	7732	11551	11551	1%			2.21	2.21		
	10280	14447	10280	14447	12364	24%			1.98	2.74		
1.00	6199	6110	6199	6110	6155	1%	5496	12%	1.21	1.19	1.08	12%
	3681	5370	3681	5370	5370	1%			1.05	1.05		
	4554	5248	4554	5248	4901	10%			0.89	1.03		
0.50	1862	2555	1862	2555	2209	22%	2290	17%	0.36	0.50	0.44	17%
	2090	2453	2090	2453	2272	11%			0.40	0.48		
	2823	1958	2823	1958	2391	26%			0.55	0.38		
0.25	1959	2048	1959	2048	2004	3%	1554	25%	0.38	0.39	0.29	28%
	1517	1374	1517	1374	1446	7%			0.28	0.25		
	1027	1397	1027	1397	1212	22%			0.18	0.26		
0.10	393	805	393	805	599	49%	660	22%	OORL	0.13	0.10	18%
	749	697	749	697	723	5%			0.12	0.11		
	720	597	720	597	659	13%			0.11	0.08		
0.00	244	356	244	356	300	26%	265	27%	OORL	OORL	OORL	OORL
	273	224	273	224	249	14%			OORL	OORL		
	159	333	159	333	246	50%			OORL	OORL		

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Table 6: Calibration 3 Summary Calculated Concentration

Calibrator Level	Nominal Value [uIU/mL]	Theranos Result [uIU/mL]	%CV	%Recovery
Calibrator 1	50.00	41.92	26%	84%
Calibrator 2	25.00	25.72	23%	103%
Calibrator 3	10.00	10.35	9%	103%
Calibrator 4	5.00	5.02	12%	100%
Calibrator 5	2.50	2.61	19%	104%
Calibrator 6	1.00	1.08	12%	108%
Calibrator 7	0.50	0.44	17%	89%
Calibrator 8	0.25	0.29	28%	117%
Calibrator 9	0.10	0.16	18%	97%
Calibrator 10	0.00	OORL	OORL	OORL

Figure 3: Nominal v. Reported Concentration



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Table 7: Calibration 4 All Data (Edison 3.5)

This calibration was performed on the Edison 3.5 and qualified against the Calibration 2 Data. All precision data was analyzed using this Calibration set.

Nominal Value [uIU/mL]	All Points		Dark Exclusion		Inter-Cartridge		Intra-Cartridge		Concentration			
	Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip 1	Tip 2	Mean	%CV
50.00	176010	172721	176010	172721	174366	1%	145561	23%	OORH	OORH	50.91	25%
	152990	163129	152990	163129	158060	5%			54.35	OORH		
	94514	114004	94514	114004	104259	13%			29.95	37.46		
25.00	101689	89269	101689	89269	95479	9%	80791	23%	32.65	28.02	24.99	25%
	94734	78166	94734	78166	86450	14%			30.03	24.07		
	68201	52689	68201	52689	60445	18%			20.65	15.56		
10.00	35840	44375	35840	44375	40108	15%	31174	36%	10.31	12.93	8.91	37%
	901	817										
	25060	19422	25060	19422	22241	18%			7.10	5.46		
5.00	16534	17522	16534	17522	17028	4%	17883	15%	4.62	4.91	5.01	15%
	17716	20059	17716	20059	18888	9%			4.96	5.64		
	13890	21579	13890	21579	17735	31%			3.87	6.08		
2.50	9943	10888	9943	10888	10416	6%	9710	8%	2.75	3.01	2.68	9%
	9885	8783	9885	8783	9334	8%			2.73	2.42		
	9094	2118	9094		9094				2.51			
1.00	3065	2157	3065		3065		3867	20%	0.81		1.03	21%
	4234	3124	4234	3124	3679	21%			1.14	0.82		
	4866	4047	4866	4047	4457	13%			1.31	1.08		
0.50	2564	2343	2564	2343	2454	6%	2074	16%	0.66	0.60	0.53	17%
	1930	2014	1930	2014	1972	3%			0.49	0.51		
	1679	1915	1679	1915	1797	9%			0.41	0.48		
0.25	1221	1108	1221	1108	1165	7%	1196	29%	0.28	0.25	0.28	35%
	735	962	735	962	849	19%			0.14	0.21		
	1479	1673	1479	1673	1576	9%			0.36	0.41		
0.10	465	429	465	429	447	6%	512	15%	OORL	OORL	OORL	OORL
	577	604	577	604	591	3%			0.10	0.11		
	565	430	565	430	498	19%			0.10	OORL		
0.00	263	211	263	211	237	16%	356	71%	OORL	OORL	OORL	OORL
	296	868	296	868	582	69%			OORL	0.18		
	256	239	256	239	248	5%			OORL	OORL		


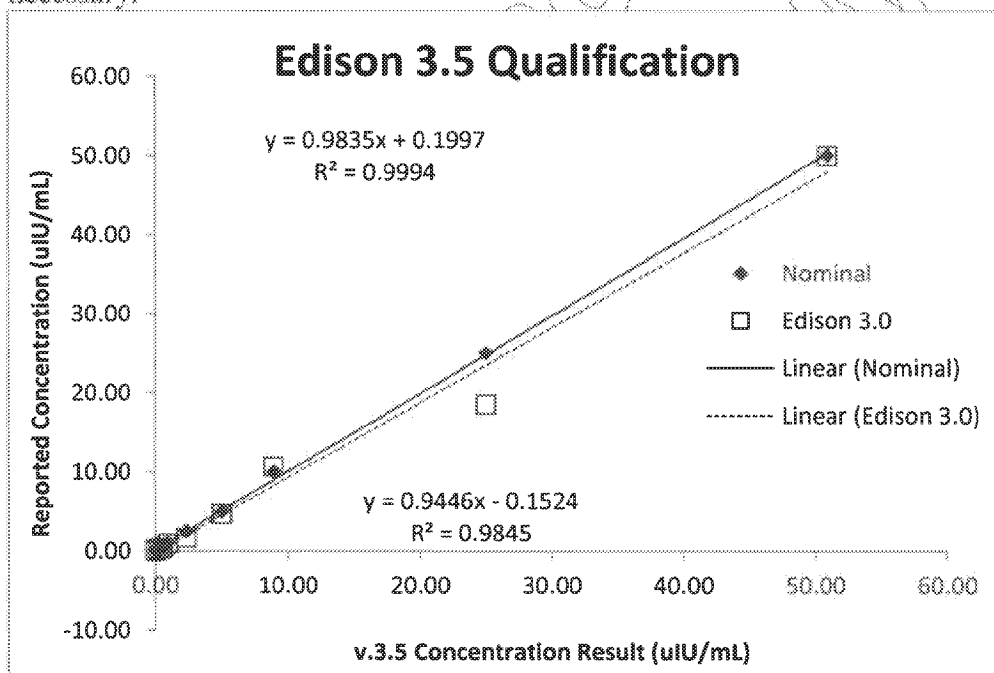
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Table 8: Calibration 3 Summary and Qualification (Edison 3.5)

Calibrator Level	Nominal Value [uIU/mL]	Theranos Result [uIU/mL]	%CV	%Recovery
Calibrator 1	50.00	50.91	25%	102%
Calibrator 2	25.00	24.99	25%	100%
Calibrator 3	10.00	8.91	37%	89%
Calibrator 4	5.00	5.01	1%	100%
Calibrator 5	2.50	2.68	9%	107%
Calibrator 6	1.00	1.03	21%	103%
Calibrator 7	0.50	0.53	17%	105%
Calibrator 8	0.25	0.28	35%	111%
Calibrator 9	0.10	OORL	OORL	OORL
Calibrator 10	0.00	OORL	OORL	OORL

Figure 4: Edison 3.5 v Nominal and Edison 3.0 results

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





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4 REFERENCE RANGE

To verify the accuracy of the Theranos System, the reference range was tested and compared to the results from the predicate method. According to C.F.R. Ch IV, § 493.1253 “Standard: Establishment and verification of performance specifications” and outlined in CLSI guideline C28A3, laboratories developing test methods need to verify the measuring interval. Additionally, by verifying the measuring interval, clinical laboratories can ensure that the calibration of the measurement procedure is correctly applicable over the range in which they report patient results and that the measuring interval they are obtaining in their laboratory is comparable to the 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. The normal range of TSH in adults is 0.4 -4uIU/mL and all euthyroid donors should have levels within this range.

Of 20 unique samples collected from normal donors, 1 patient had TSH levels outside of the reference range. This sample was confirmed via the predicate method listed in section 1.2. Overall, 95% of the patients tested fell within the reference range, and is acceptable for verification of the reference range. There is poor correlation between the predicate method results and the Theranos results, however all averaged data points were within the TSH reference range. The poor correlation between methods may be due to the EDTA anticoagulant which is not be suitable for testing in the predicate method. Calculated concentrations are based on the mean RLU of 3 cartridges tested.

Table 9: Normal Patient Samples

Reported Value (uIU/mL)	All Tips		Dark Exclusion		Inter-Cartridge		Intra-Cartridge		Concentration			%CV	%Recovery
	Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip1	Tip2	Mean		
0.934	9125	9589	9125	9589	9357	4%	9723	7%	2.25	2.36	2.39	7%	256%
	9579	9985	9579	9985	9782	3%			2.35	2.45			
	9058	11002	9058	11002	10030	14%			2.23	2.68			
0.576	6572	5741	6572	5741	6157	10%	5195	17%	1.64	1.44	1.30	17%	226%
	4440	5414	4440	5414	4927	14%			1.11	1.36			
	4239	4766	4239	4766	4503	8%			1.06	1.20			
0.34	3719	4036	3719	4036	3878	6%	4249	18%	0.93	1.01	1.06	18%	313%
	3981	3386	3981	3386	3684	11%			0.99	0.84			
	5199	5175	5199	5175	5187	0%			1.30	1.30			
OORL	301	348	301	348	325	10%	279	15%	OORL	OORL	OORL	OORL	OORL
	252	267	252	267	260	4%			OORL	OORL			
	225	283	225	283	254	16%			OORL	OORL			
1.89	4100	20773		20773	20773		17972	12%		4.86	4.24	11%	224%
	2181	18268		18268	18268					4.31			
	16880	15966	16880	15966	16423	4%			4.00	3.80			
0.503	3837	4211	3837	4211	4024	7%	3943	6%	0.96	1.05	0.98	6%	196%



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	5	39	DARK	DARK															
	4012	3710	4012	3710	3861	6%			1.00	0.92									
	5636	5756	5636	5756	5696	1%			1.41	1.44									
0.541	5600	5511	5600	5511	5556	1%	5680	3%	1.40	1.38	1.42	3%	263%						
	5898	3	5898	DARK	5898				1.48										
	5188	5493	5188	5493	5341	4%			1.30	1.38									
0.526	4958	4786	4958	4786	4872	2%	5060	6%	1.24	1.20	1.27	6%	241%						
	4687	5246	4687	5246	4967	8%			1.18	1.32									
	3699	59898	3699	59898	31799	125%			0.92	1.00									
0.885	10806	11682	10806	11682	11244	6%	18430	112%	2.64	2.84	4.34	107%	491%						
	12673	11823	12673	11823	12248	5%			3.06	2.87									
	5616	17	5616	DARK	5616				1.41										
0.71	283	6839		6839	6839		6760	12%		1.71	1.69	11%	238%						
	7310	7275	7310	7275	7293	0%			1.82	1.81									
	9729	9136	9729	9136	9433	4%			2.39	2.25									
0.987	8787	8916	8787	8916	8852	1%	8870	6%	2.17	2.20	2.19	6%	222%						
	8611	8041	8611	8041	8326	5%			2.13	1.99									
	9722	9468	9722	9468	9595	3%			2.39	2.33									
0.823	7962	8825	7962	8825	8394	7%	9118	8%	1.98	2.18	2.25	8%	273%						
	1800	9615		9615	9615					2.36									
	4059	4431	4059	4431	4245	6%			1.01	1.11									
0.448	5934	5458	5934	5458	5696	6%	4897	14%	1.49	1.37	1.23	14%	274%						
	4522	4975	4522	4975	4749	7%			1.13	1.25									
	4813	4895	4813	4895	4854	1%			1.21	1.23									
0.445	5707	6450	5707	6450	6079	9%	5246	13%	1.43	1.61	1.32	13%	296%						
	4973	4629	4973	4629	4801	5%			1.25	1.16									
	13645	15072	13645	15072	14359	7%			3.28	3.60									
0.896	9752	11785	9752	11785	10769	13%	12015	16%	2.39	2.86	2.91	15%	325%						
	11019	10817	11019	10817	10918	1%			2.69	2.64									
	6594	6321	6594	6321	6458	3%			1.65	1.58									
0.626	6714	5840	6714	5840	6277	10%	6456	14%	1.68	1.46	1.61	14%	258%						
	5285	7979	5285	7979	6632	29%			1.33	1.98									
	4300	5025	4300	5025	4663	11%			1.08	1.26									
0.512	1264	6334		6334	6334	#DIV/0!	5149	16%	OORL	1.58	1.29	16%	252%						
	5573	4515	5573	4515	5044	15%			1.40	1.13									
	7322	7704	7322	7704	7513	4%			1.82	1.91									
0.618	6914	5183	6914	5183	6049	20%	6268	19%	1.73	1.30	1.57	18%	254%						
	5413	5074	5413	5074	5244	5%			1.36	1.27									
	3972	4125	3972	4125	4049	3%			0.99	1.03									
0.339	3241	3800	3241	3800	3521	11%	3676	10%	0.80	0.95	0.91	10%	270%						
	3592	3324	3592	3324	3458	5%			0.89	0.82									
	7651	7646	7651	7646	7649	0%			1.90	1.90									
0.655	30	109	DARK	DARK			7649	0%			1.90	0%	290%						
	2	23	DARK	DARK															

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Table 10: Reference Range summary

Sample ID	Reported Value [uIU/mL]	Theranos Result [uIU/mL]	%CV	%Recovery
Patient 1	0.934	2.39	7%	256%
Patient 2	0.576	1.30	17%	226%
Patient 3	0.34	1.06	18%	313%
Patient 4	OORL	OORL	OORL	OORL
Patient 5	1.89	4.24	11%	224%
Patient 6	0.503	0.98	6%	196%
Patient 7	0.541	1.42	3%	263%
Patient 8	0.526	1.27	6%	241%
Patient 9	0.885	4.34	107%	491%
Patient 10	0.71	1.69	11%	238%
Patient 11	0.987	2.19	6%	222%
Patient 12	0.823	2.25	8%	273%
Patient 13	0.448	1.23	14%	274%
Patient 14	0.445	1.32	13%	296%
Patient 15	0.896	2.91	15%	325%
Patient 16	0.626	1.61	14%	258%
Patient 17	0.512	1.29	16%	252%
Patient 18	0.618	1.57	18%	254%
Patient 19	0.339	0.91	10%	270%
Patient 20	0.655	1.90	0%	290%

4 PRECISION

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

- 4.1 The report will include scatter plots, precision summary tables and conclusions about the performance claim(s) regarding within-run (repeatability), between-day, between-lot and within laboratory precision.
- 4.2 Acceptance criteria: The %CV of replicates at each concentration of the samples should not be more than 20% (25% at LLOQ and ULOQ) for ELISA assays.

Calculated concentrations in the precision experiment are based on the mean RLU of 3 cartridges tested excluding outliers and dark count tips. All clinical samples will be analyzed in this manner.

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Figure 5: Level 1 % from the Mean

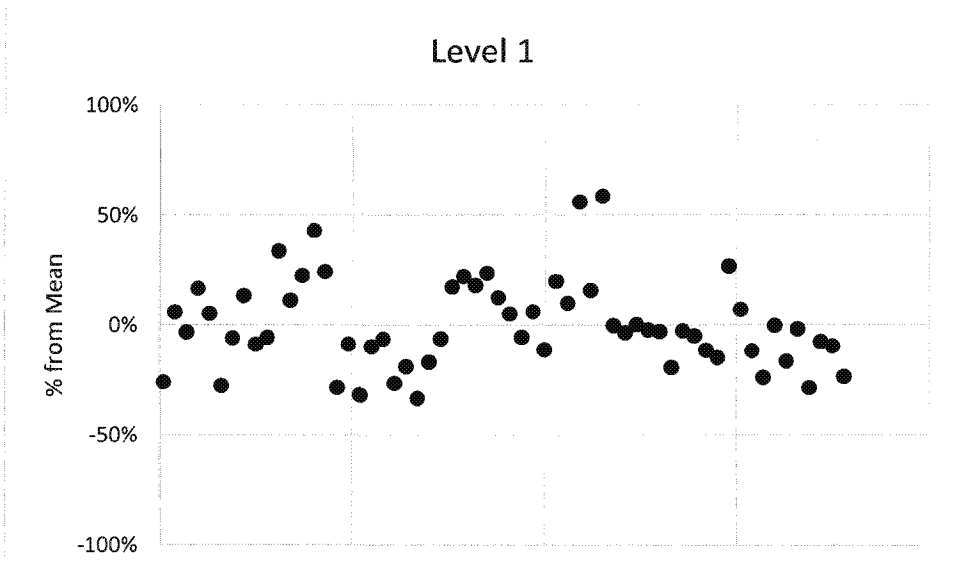
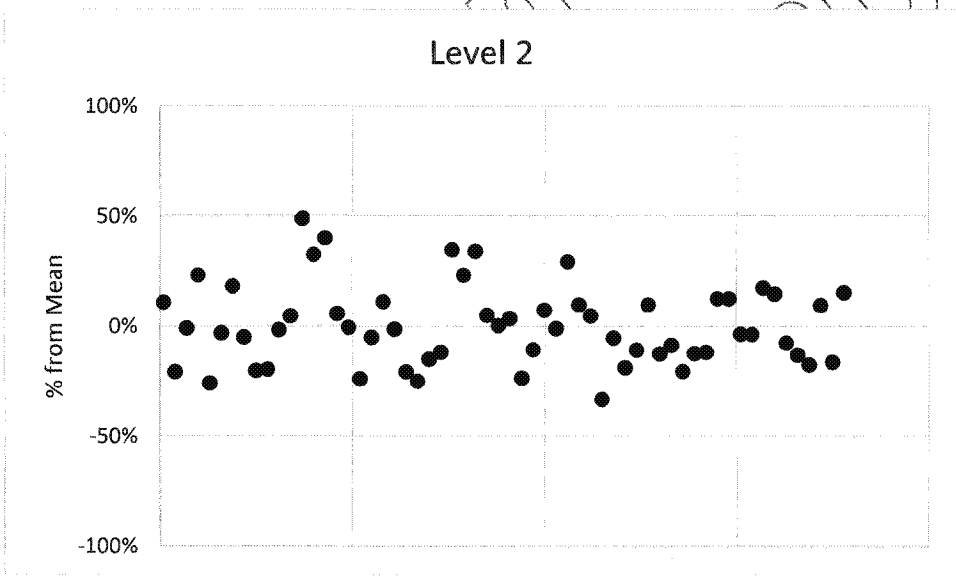
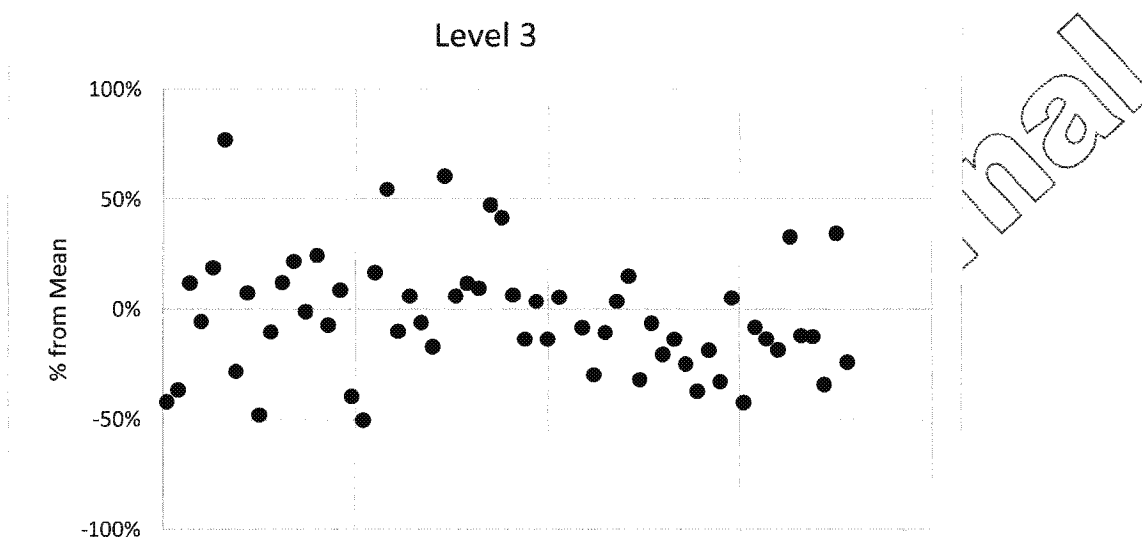


Figure 6: Level 2 % from the Mean



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Figure 7: Level 3 % from the Mean



The precision data is summarized in the table below:

Table 11: Precision Summary

Level(uIU/mL)	Precision (%)
0.2	28
2	18
20	19

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5 ACCURACY/COMPARABILITY

To test the accuracy of the assay on the Theranos System, 103 unique patient samples were screened on the predicate method (Siemens, Immulite) and testing on the Theranos System. Of these samples 51 were within the reference range (0.3-5uIU/mL), 27 were below the reference range, and 25 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.

Calculated concentrations are based on the average RLU of 3 cartridges excluding outliers and dark count tips.

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Table 12: Clinical Correlation Historical Data

During the development process, clinical correlation was performed. This data was retrieved from the ELISA Assay Development documents.

Sample ID	Reported Value [uIU/mL]	Theranos Result [uIU/mL]	% Recovery
TSH01	0.749	0.72	96%
TSH02	0.925	0.87	94%
TSH03	0.943	0.91	97%
TSH04	1.75	2.28	130%
TSH05	1.87	0.85	45%
TSH06	1.6	2.18	136%
TSH07	1.58	1.85	117%
TSH08	2.13	2.26	106%
TSH09	3.25	1.77	54%
TSH10	25.8	30.34	118%
TSH11	2.85	2.87	101%
TSH12	3.48	3.13	90%
TSH13	4.63	4.08	88%
TSH14	6.99	6.48	93%
TSH15	5.17	5.69	110%
TSH16	0.28	0.29	104%
TSH17	0.025	0.05	200%
TSH18	0.155	0.14	90%
TSH19	0.761	0.86	113%
TSH20	2.95	1.79	61%
TSH21	9.62	11.4	119%
TSH22	10.1	11.4	113%
TSH23	2.51	3.11	124%

Table 13: Clinical Sample Predicate Method Correlation Summary

Sample ID	Reported Value [uIU/mL]	Theranos Result [uIU/mL]	% Recovery
N1	4.44	3.63	82%
N2	5.15	3.17	62%
N3	4.14	4.44	107%
N4	4.87	4.18	86%
N5	3.97	0.38	9%
N6	4.79	3.60	75%
N7	1.91	1.31	68%
N8	2.40	2.11	88%
N9	3.07	3.19	104%
N10	1.96	1.83	93%
N11	4.32	3.69	85%
N12	1.17	1.25	107%
N13	0.99	0.88	89%
N14	3.95	3.18	81%
N15	0.90	1.00	111%

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N16	1.55	1.58	102%
N17	3.28	2.64	80%
N18	1.45	1.67	115%
N19	0.59	0.44	75%
N20	2.23	1.46	66%
SM1	1.22	1.39	114%
SM2	1.15	1.06	92%
SM3	2.53	2.96	117%
SM4	2.00	1.97	99%
SF1	0.86	0.94	109%
SF2	2.18	2.27	104%
SF3	0.66	0.67	103%
SF4	2.98	2.98	100%
SF5	1.97	1.98	100%
1	0.49	0.60	122%
2	2.76	2.68	97%
3	1.19	1.38	116%
4	0.89	0.94	106%
5	1.11	1.00	90%
L1	0.23	0.34	146%
L2	0.26	0.25	97%
L3	0.05	OORL	OORL
L4	0.02	OORL	OORL
L5	0.04	0.19	500%
L6	0.17	0.18	107%
L7	0.29	0.30	101%
L8	0.10	0.09	94%
L9	0.18	0.20	112%
L10	0.13	0.14	102%
L11	0.31	0.28	89%
L12	3.52	3.68	105%
L13	3.31	3.86	117%
L14	0.24	0.45	190%
L15	0.06	OORL	OORL
L16	0.06	OORL	OORL
L17	0.20	0.31	159%
L18	0.15	0.25	171%
L19	0.31	0.42	137%
L20	0.30	0.32	109%
L21	0.03	OORL	OORL
L22	0.01	OORL	OORL
L23	0.13	0.11	85%
L24	0.19	0.38	199%
L25	0.36	0.41	116%
L26	0.05	0.23	486%
II1	33.30	37.65	113%
H2	35.30	46.63	132%
H3	21.70	21.79	100%

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H4	40.30	46.98	117%
H5	6.67	6.43	96%
H6	9.08	10.96	121%
H7	11.30	15.77	140%
H8	11.30	11.68	103%
H9	16.70	19.40	116%
H10	4.47	7.25	162%
H11	11.40	11.91	104%
H12	10.10	9.83	97%
H13	16.50	16.71	101%
H14	6.12	5.09	83%
H15	9.85	5.55	56%
H16	7.63	5.61	74%
H17	10.60	8.07	76%
H18	10.70	9.14	85%
H19	16.90	13.68	81%
H20	9.12	8.64	95%

Table 14: Bias Correction

Only values less than 20uIU/mL were used to correct for bias between the Theranos System and the predicate method.

Predicate Method	Theranos System	Predicate Method	Theranos-Corrected
4.44	3.63	4.44	3.88
5.15	3.17	5.15	3.40
4.14	4.44	4.14	4.70
4.87	4.18	4.87	4.44
3.97	0.38	3.97	0.53
4.79	3.60	4.79	3.84
1.91	1.09	1.91	1.26
2.4	2.11	2.40	2.31
3.07	3.19	3.07	3.42
1.96	1.83	1.96	2.02
4.32	3.11	4.32	3.34
1.17	0.82	1.17	0.99
0.992	0.88	0.99	1.05
3.95	3.18	3.95	3.41
0.904	1.00	0.90	1.17
1.55	1.58	1.55	1.76
3.28	2.64	3.28	2.86
1.45	1.67	1.45	1.86
0.588	0.44	0.59	0.60
2.23	1.22	2.23	1.40
1.22	0.68	1.22	0.84
1.15	0.70	1.15	0.87
2.53	2.96	2.53	3.18
2	1.97	2.00	2.17
0.864	0.78	0.86	0.94
2.18	2.27	2.18	2.47

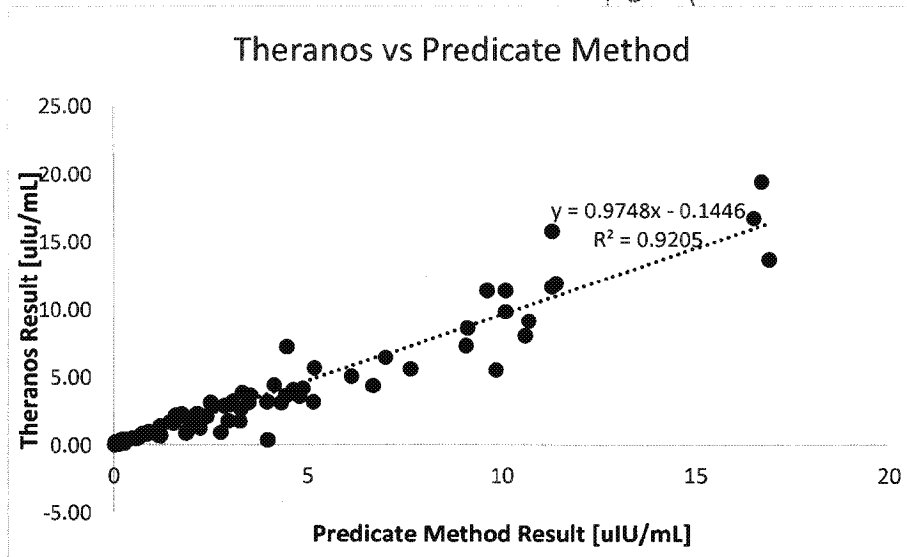
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0.655	0.55	0.66	0.71
2.98	2.98	2.98	3.20
1.97	1.98	1.97	2.18
0.49	0.48	0.49	0.65
2.76	0.93	2.76	1.10
1.19	1.38	1.19	1.57
0.89	0.94	0.89	1.11
1.11	1.00	1.11	1.17
0.231	0.34	0.23	0.49
0.262	0.25	0.26	0.41
0.038	0.19	0.04	0.34
0.168	0.18	0.17	0.33
0.294	0.30	0.29	0.45
0.098	0.09	0.10	0.24
0.18	0.20	0.18	0.35
0.134	0.10	0.13	0.25
0.314	0.28	0.31	0.44
3.52	3.68	3.52	3.92
3.31	3.86	3.31	4.11
0.235	0.45	0.24	0.61
0.197	0.31	0.20	0.47
0.146	0.25	0.15	0.40
0.307	0.33	0.31	0.49
0.298	0.18	0.30	0.33
0.132	0.11	0.13	0.26
0.191	0.38	0.19	0.54
0.355	0.41	0.36	0.57
0.047	0.23	0.05	0.38
6.67	4.39	6.67	4.65
9.08	7.36	9.08	7.69
11.3	15.77	11.30	16.33
11.3	11.68	11.30	12.13
16.7	19.40	16.70	20.05
4.47	7.25	4.47	7.59
11.4	11.91	11.40	12.37
10.1	9.83	10.10	10.23
16.5	16.71	16.50	17.29
6.12	5.09	6.12	5.37
9.85	5.55	9.85	5.84
7.63	5.61	7.63	5.90
10.6	8.07	10.60	8.42
10.7	9.14	10.70	9.53
16.9	13.68	16.90	14.18
9.12	8.64	9.12	9.01
0.749	0.72	0.75	0.89
0.925	0.87	0.93	1.04
0.943	0.91	0.94	1.08
1.75	2.28	1.75	2.49
1.87	0.85	1.87	1.02
1.6	2.18	1.60	2.38

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1.58	1.85	1.58	2.05
2.13	2.26	2.13	2.47
3.25	1.77	3.25	1.96
2.85	2.87	2.85	3.09
3.48	3.13	3.48	3.36
4.63	4.08	4.63	4.33
6.99	6.48	6.99	6.80
5.17	5.69	5.17	5.99
0.28	0.29	0.28	0.45
0.025	0.05	0.03	0.20
0.155	0.14	0.16	0.29
0.761	0.86	0.76	1.03
2.95	1.79	2.95	1.98
9.62	11.40	9.62	11.84
10.1	11.40	10.10	11.84
2.51	3.11	2.51	3.34

Figure 8: Theranos system v. Predicate Method Result



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Figure 9: Theranos-Corrected v. Predicate Method

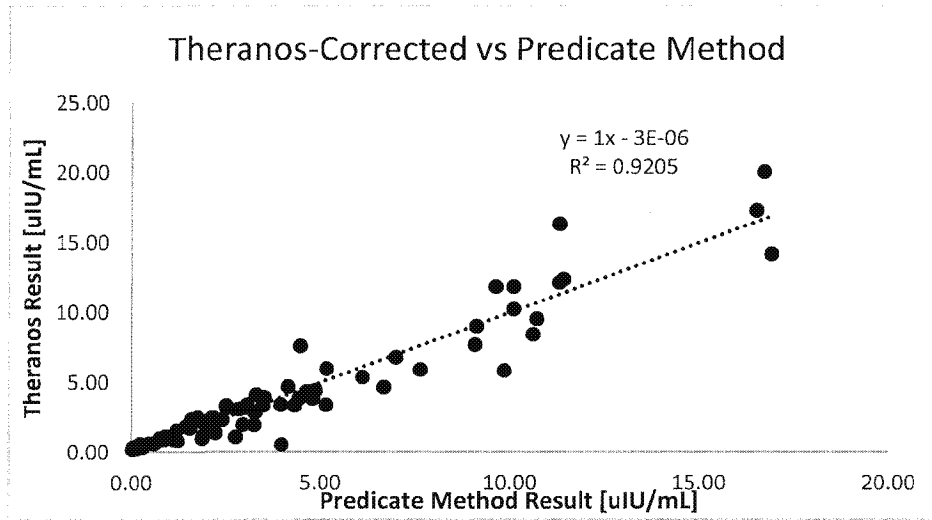


Table 13: Method Comparison Summary

Method Comparison			
Level (uIU/mL)	Precision (%)	Total Error (%)	Allowable Bias (%)
0.2	28	32	4
2	18	22	4
20	19	24	5


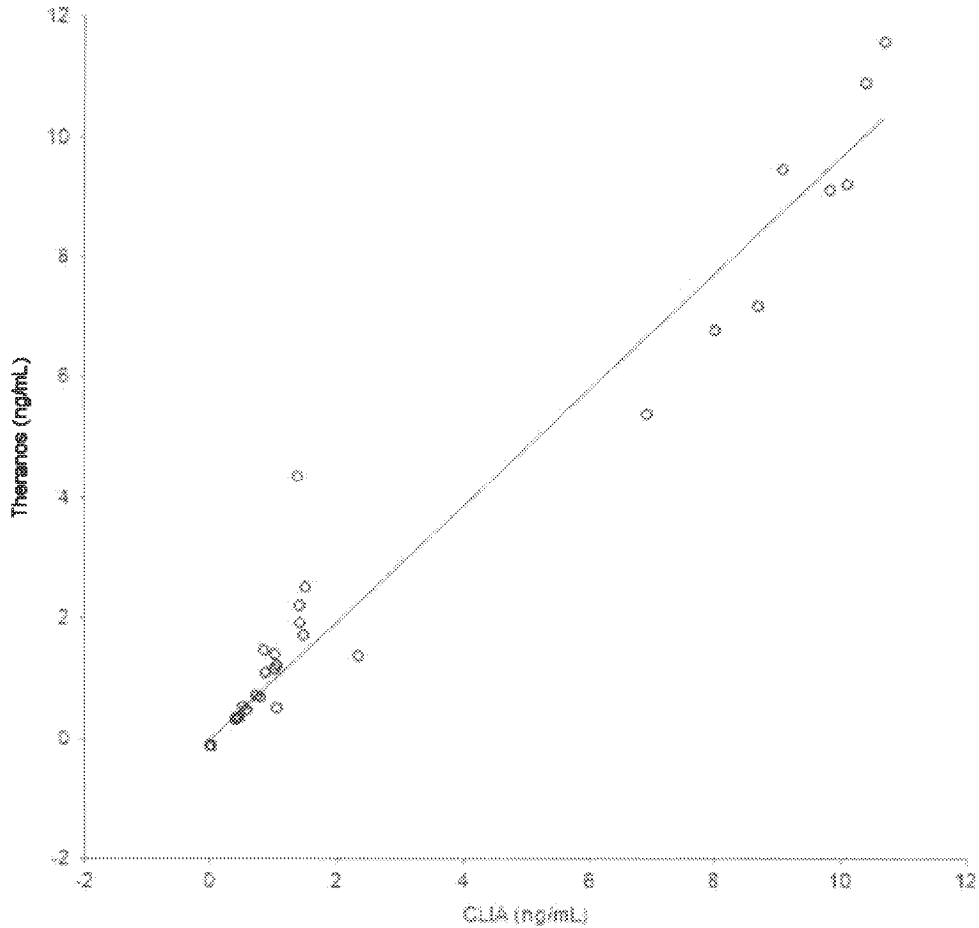
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Figure 10: Scatter Plot CLSI guideline EP09-A2-IR section 4.2

Scatter plot

CLSI: guideline EP09-A2-IR section 4.2




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

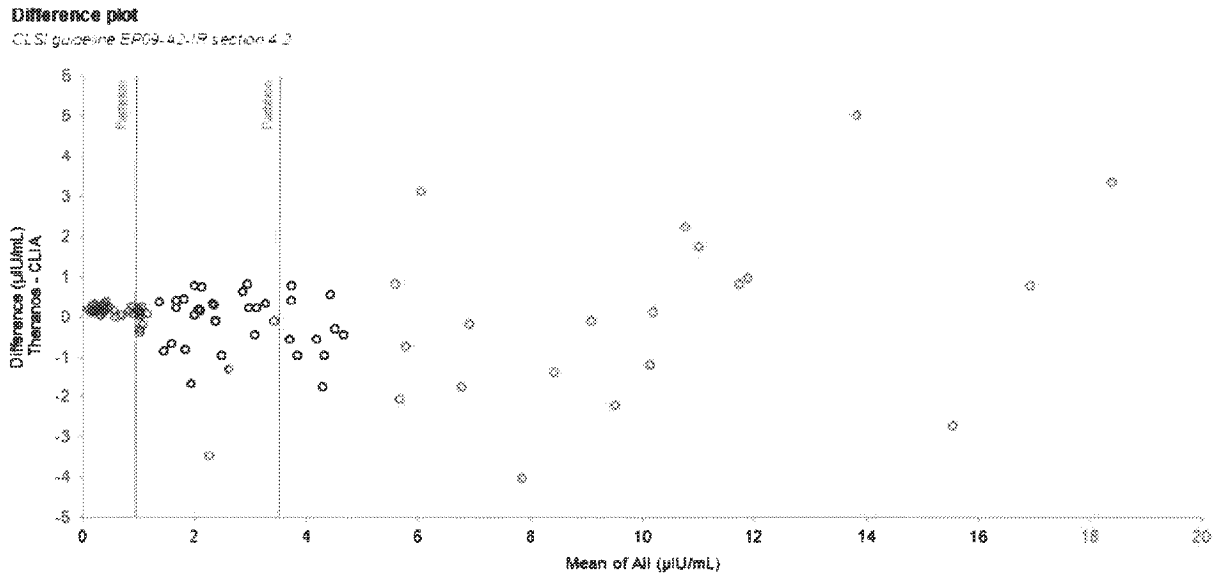


Table 16: Comparability CLSI guideline EP09-A2-IR section 7

Comparability

CLSI guideline EP09-A2-IR section 7

Level ID	Value	Difference	SE	95% CI	Allowable difference
1	4.00000000	-0.15058161	0.09422452	-0.338874292 to 0.03771	0.160000000
2	11.30000000	-0.41743502	0.24634058	-0.909707408 to 0.07483	0.565000000
3	23.00000000	-0.84513158	0.52013902	-1.384546479 to 0.19428	1.150000000

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


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Table 17: Ordinary Linear Fit CLSI guideline EP09-A2-IR section 5.1

Ordinary linear fit

CLSI guideline EP09-A2-IR section 5.1

	n	65		
	Parameter	Estimate	SE	95% CI
	Constant (intercept)	-0.00436056	0.07924634	-0.162721755 to 0.15400
	Proportional (slope)	0.963	0.0239	0.916 to 1.011
	Sy.x	0.576442281		

6 DILUTION LINEARITY

Sample H4 was selected from the Accuracy/Comparability study above and serially diluted to a total of 8 points to test the linearity. H4 was diluted using a pooled sample of L21 and L22. The nominal values of each level were calculated based on the value of sample H4 as reported by the predicate method (Siemens Immulite). 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 greater than 0.95.

Calculated concentrations are based on the average RLU of 3 cartridges excluding outliers and dark count tips. When comparing the nominal values to the Theranos results, the linearity is acceptable.

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Table 18: Dilution Linearity

Sample [uIU/mL]	All Tips		Dark Exclusion		Inter-Cartridge		Intra-Cartridge		Concentration [uIU/mL]				%Recovery
	Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip 1	Tip 2	Mean	%CV	
40.300	169907	191659	169907	191659	180783	9%	155458	19%	47.35	56.31	41.90	26%	104%
	169620	164591	169620	164591	167106	2%			47.24	45.30			
	113319	123651	113319	123651	118485	6%			27.96	31.15			
20.150	81539	83797	81539	83797	82668	2%	82256	8%	19.08	16.68	19.27	9%	96%
	93860	81818	93860	81818	87839	10%			22.38	19.16			
	79453	73066	79453	73066	76260	6%			18.54	16.92			
10.075	31680	35274	31680	35274	33477	8%	36333	14%	7.23	8.04	8.27	14%	82%
	30	5	DARK	DARK									
	42045	5	42045	DARK	42045				9.55				
5.038	16515	15656	16515	15656	16086	4%	18362	11%	3.92	3.73	4.33	11%	86%
	18972	20164	18972	20164	19568	4%			4.46	4.72			
	21076	17788	21076	17788	19432	12%			4.92	4.20			
2.519	10257	9562	10257	9562	9910	5%	11494	11%	2.51	2.35	2.79	11%	111%
	12424	11705	12424	11705	12065	4%			3.01	2.84			
	12868	12145	12868	12145	12507	4%			3.11	2.94			
1.259	4578	5492	4578	5492	5035	13%	5140	8%	1.18	1.38	1.29	8%	102%
	5432	5550	5432	5550	5491	2%			1.36	1.39			
	4685	5102	4685	5102	4894	6%			1.17	1.28			
0.630	2532	2894	2532	2894	2713	9%	3002	13%	0.61	0.71	0.74	14%	117%
	2611	3091	2611	3091	2851	12%			0.63	0.76			
	3426	3457	3426	3457	3442	1%			0.85	0.86			
0.315	299	323	299	323	311	5%	333	12%	OORL	OORL	OORL	OORL	OORL
	301	320	301	320	311	4%			OORL	OORL			
	346	406	346	406	376	11%			OORL	OORL			

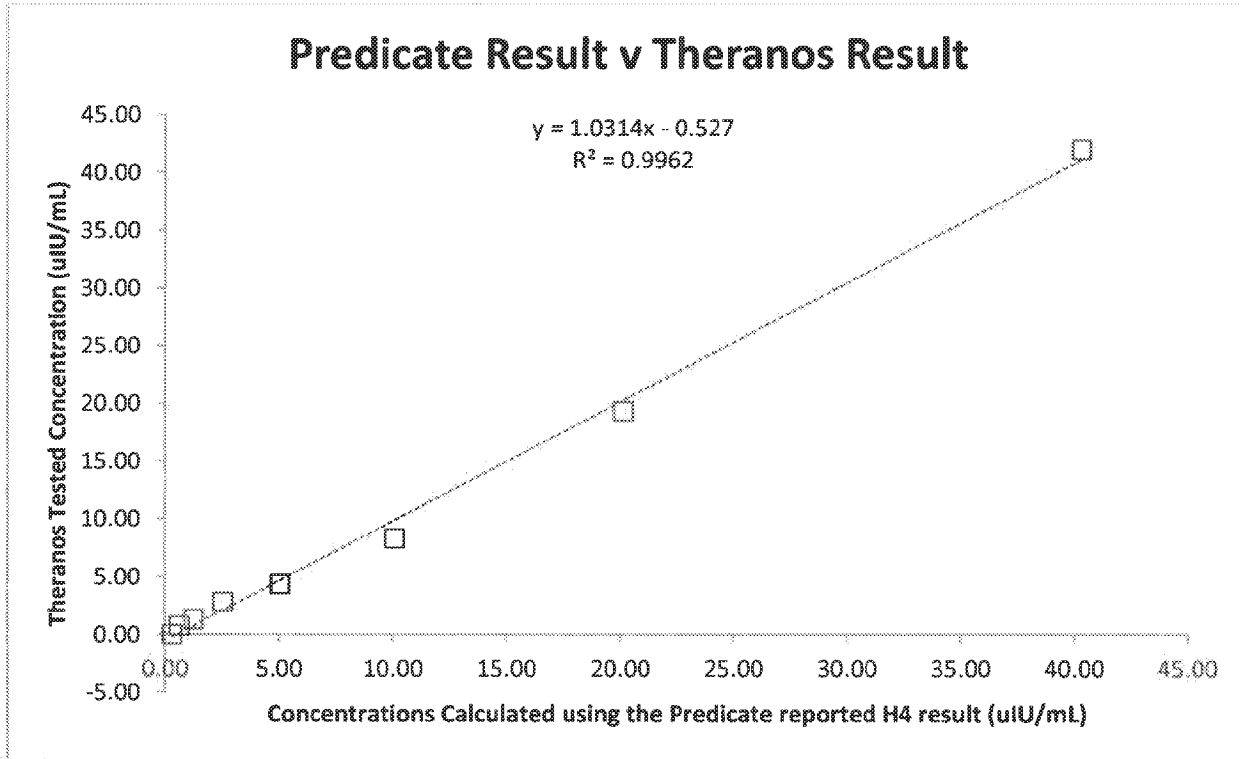
Table 19: Dilution Linearity Summary

The nominal dilution levels were calculated using the predicate method result for Sample H4. The recovery is acceptable once dark count tips were excluded from the mean calculations.

Sample ID	Nominal Value [uIU/mL]	Theranos Result [uIU/mL]	%CV	%Recovery
High Patient Sample	40.300	41.90	26%	104%
1/2	20.150	19.27	9%	96%
1/4	10.075	8.27	14%	82%
1/8	5.038	4.33	11%	86%
1/16	2.519	2.79	11%	111%
1/32	1.259	1.29	8%	102%
1/64	0.630	0.74	14%	117%
1/128	0.315	OORL	OORL	OORL

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Figure 12: Dilution Linearity



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 of TSH in adults is 0.4-4uIU/mL.

20 unique patients donated 2 venous tubes of blood and 4 fingerstick samples. Out of these patient samples one tested outside of the reference range. Overall, 95% of the patient samples fell within the reference range.



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Table 20: Venous v. Fingerstick

Sample Type	All Tips		Dark Exclusion		Inter-Cartridge		Intra-Cartridge			
	Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Mean	%CV
Venous 1	2990	2695	2990	2695	2843	7%	3390	21%	3743	15%
Venous 2	3563	4312	3563	4312	3938	13%				
Fingerstick 1	4209	4460	4209	4460	4335	4%				
Fingerstick 2	3502	4203	3502	4203	3853	13%				
Fingerstick 3	3964	6	3964	DARK	3964		3945	10%		
Fingerstick 4	3391	3889	3391	3889	3640	10%				
Venous 1	3445	3733	3445	3733	3589	6%	3733	10%	3751	14%
Venous 2	3059	4907	3059	4907	3983	32%				
Fingerstick 1	3861	3986	3861	3986	3924	2%				
Fingerstick 2	3348	4249	3348	4249	3799	17%				
Fingerstick 3	3220	3688	3220	3688	3454	10%				
Fingerstick 4	3484	4027	3484	4027	3756	10%				
Venous 1	2764	3338	2764	3338	3051	13%	3267	12%	3083	12%
Venous 2	3248	3716	3248	3716	3482	10%				
Fingerstick 1	3371	3102	3371	3102	3237	6%				
Fingerstick 2	3050	3103	3050	3103	3077	1%				
Fingerstick 3	2698	2436	2698	2436	2567	7%	2960	11%		
Fingerstick 4										
Venous 1	4770	3	4770	DARK	4770		4862	32%	4808	15%
Venous 2	6452	3363	6452	3363	4908	45%				
Fingerstick 1	4287	4401	4287	4401	4344	2%				
Fingerstick 2	5176	4908	5176	4906	5041	4%				
Fingerstick 3	4901	4886	4901	4886	4894	0%	4789	7%	4478	12%
Fingerstick 4	5090	4661	5090	4661	4876	6%				
Venous 1	4858	5098	4858	5098	4978	3%				
Venous 2	4466	4968	4466	4968	4717	8%				
Fingerstick 1	4133	3835	4133	3835	3984	5%	4293	13%	6168	10%
Fingerstick 2	4287	4308	4287	4308	4298	0%				
Fingerstick 3	3363	4462	3363	4462	3913	20%				
Fingerstick 4	5021	4931	5021	4931	4976	1%				
Venous 1	7846	8142	7846	8142	7994	3%	7994	3%	7967	17%
Venous 2	4	24	DARK	DARK						
Fingerstick 1	10633	9046	10633	9046	9840	11%				
Fingerstick 2	6673	7098	6673	7098	6886	4%				
Fingerstick 3							7958	20%		
Fingerstick 4	7672	6626	7672	6626	7149	10%				
Venous 1	6667	6233	6667	6233	6450	5%	6690	15%	6481	13%
Venous 2	5270	6503	5270	6503	5887	15%				
Fingerstick 1	5489	7751	5489	7751	6620	24%				
Fingerstick 2	4	46	DARK	DARK						
Fingerstick 3	7156	7761	7156	7761	7459	6%				
Fingerstick 4	6230	5751	6230	5751	5991	6%				



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Venous 1	2785	3460	2785	3460	3123	15%	3517	17%		
Venous 2	3572	4249	3572	4249	3911	12%				
Fingerstick 1	3061	3941	3061	3941	3501	18%			3363	12%
Fingerstick 2	2974	3103	2974	3103	3039	3%				
Fingerstick 3	3147	3325	3147	3325	3236	4%	3286	9%		
Fingerstick 4	3296	3440	3296	3440	3368	3%				
Venous 1	7735	8063	7735	8063	7899	3%	7847	1%		
Venous 2	8033	7557	8033	7557	7795	4%			7988	12%
Fingerstick 1	9492	8540	9492	8540	9016	7%				
Fingerstick 2	6250	6668	6250	6668	6459	5%				
Fingerstick 3	8668	8926	8668	8926	8797	2%	8030	14%		
Fingerstick 4	8417	7510	8417	7510	7964	8%				
Venous 1	575	19934		19934	19934					
Venous 2	22646	24594	22646	24594	23630	6%	22391	10%		
Fingerstick 1	18001	20793	18001	20793	19397	10%			18523	19%
Fingerstick 2	13682	15495	13682	15495	14589	9%				
Fingerstick 3	13682	15495	13682	15495	14589	9%	17072	17%		
Fingerstick 4	19919	19511	19919	19511	19715	1%				
Venous 1	5888	3891	5888	3891	4890	29%	4993	17%		
Venous 2	4877	5317	4877	5317	5097	6%				
Fingerstick 1	23601	3	23601	DARK	23601				13725	54%
Fingerstick 2	18001	20793	18001	20793	19397	10%	18715	18%		
Fingerstick 3	13682	15495	13682	15495	14589	9%				
Fingerstick 4	19919	19511	19919	19511	19715	1%				
Venous 1	103154	115531	103154	115531	109343	8%	131617	24%		
Venous 2	131109	176673	131109	176673	153891	21%				
Fingerstick 1	126379	125470	126379	125470	125925	1%			121830	19%
Fingerstick 2	123031	111195	123031	111195	117113	7%				
Fingerstick 3	100682	89607	100682	89607	95145	8%	116937	14%		
Fingerstick 4	116003	143129	116003	143129	129566	15%				
Venous 1	5611	5432	5611	5432	5522	2%	5046	11%		
Venous 2	4524	4618	4524	4618	4571	1%				
Fingerstick 1	4962	4901	4962	4901	4932	1%			5157	12%
Fingerstick 2	3888	5949	3888	5949	4919	30%				
Fingerstick 3	5291	5754	5291	5754	5523	6%	5213	12%		
Fingerstick 4	5516	5441	5516	5441	5479	1%				
Venous 1	7337	7887	7337	7887	7612	5%	7007	13%		
Venous 2	5710	7095	5710	7095	6403	15%				
Fingerstick 1	6685	7644	6685	7644	7165	9%			7157	10%
Fingerstick 2	6478	7125	6478	7125	6802	7%				
Fingerstick 3	1466	8255		8255	8255		7243	8%		
Fingerstick 4	7190	7323	7190	7323	7257	1%				
Venous 1	2851	2762	2851	2762	2807	2%	2710	5%		
Venous 2	2710	2515	2710	2515	2613	5%			2331	17%
Fingerstick 1	101	2370	DARK	2370	2370					
Fingerstick 2	1763	1808	1763	1808	1786	2%	2078	14%		



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Fingerstick 3	2038	52576	2038		2038								
Fingerstick 4	2039	2449	2039	2449	2244	13%							
Venous 1	8498	6768	8498	6768	7633	16%	8464	17%					
Venous 2	8302	10287	8302	10287	9295	15%							
Fingerstick 1	7743	7815	7743	7815	7779	1%							
Fingerstick 2	7435	7697	7435	7697	7566	2%						8207	13%
Fingerstick 3	4	54	DARK	DARK			8036	17%					
Fingerstick 4	7654	9869	7654	9869	8762	18%							
Venous 1	6046	5884	6046	5884	5965	2%	5926	8%					
Venous 2	5332	6443	5332	6443	5888	13%							
Fingerstick 1	8721	7812	8721	7812	8267	8%						7674	20%
Fingerstick 2	10513	9250	10513	9250	9882	9%							
Fingerstick 3	8800	7235	8800	7235	8018	14%	8549	12%					
Fingerstick 4	7522	8535	7522	8535	8029	9%							
Venous 1	5327	6129	5327	6129	5728	10%							
Venous 2	4706	4421	4706	4421	4564	4%	5146	15%					
Fingerstick 1	3952	3952	3952	3952	3952	0%						4495	15%
Fingerstick 2	3873	4308	3873	4308	4091	8%							
Fingerstick 3	4459	4533	4459	4533	4496	1%	4170	6%					
Fingerstick 4	4082	4198	4082	4198	4140	2%							
Venous 1	8449	7967	8449	7967	8208	4%	9080	11%					
Venous 2	10143	9679	10143	9679	9911	3%							
Fingerstick 1	8890	9673	8890	9673	9282	6%						9334	10%
Fingerstick 2	8267	8589	8267	8589	8428	3%	9471	9%					
Fingerstick 3	10157	10937	10157	10937	10547	5%							
Fingerstick 4	9772	9484	9772	9484	9628	2%							
Venous 1	9394	9557	9394	9557	9476	1%	9821	5%					
Venous 2	9910	10423	9910	10423	10167	4%							
Fingerstick 1	8579	8890	8579	8890	8735	3%						9652	6%
Fingerstick 2	9101	10351	9101	10351	9726	9%							
Fingerstick 3	9101	10351	9101	10351	9726	9%	9585	7%					
Fingerstick 4	10254	9872	10254	9872	10063	3%							
Fingerstick 5	9607	9741	9607	9741	9674	1%							



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Table 21: Blood Collection Device Comparison Summary

Sample ID	Sample Type	Theranos Result [uIU/mL]	%CV	% difference
Patient 1	Venous 1	0.62	23%	15%
	Fingerstick 1	0.72	11%	
Patient 2	Venous 1	0.69	23%	-2%
	Fingerstick 1	0.68	10%	
Patient 3	Venous 1	0.59	13%	-11%
	Fingerstick 1	0.53	12%	
Patient 4	Venous 1	0.90	34%	-2%
	Fingerstick 1	0.89	7%	
Patient 5	Venous 1	0.90	6%	-14%
	Fingerstick 1	0.79	13%	
Patient 6	Venous 1	1.53	3%	0%
	Fingerstick 1	1.52	21%	
Patient 7	Venous 1	1.16	11%	8%
	Fingerstick 1	1.27	16%	
Patient 8	Venous 1	0.64	18%	-8%
	Fingerstick 1	0.60	10%	
Patient 9	Venous 1	1.50	3%	-3%
	Fingerstick 1	1.54	15%	
Patient 10	Venous 1	4.47	11%	-33%
	Fingerstick 1	3.37	17%	
Patient 11	Venous 1	0.93	18%	75%
	Fingerstick 1	3.71	19%	
Patient 12	Venous 1	29.67	27%	-14%
	Fingerstick 1	25.94	16%	
Patient 13	Venous 1	0.94	12%	3%
	Fingerstick 1	0.97	13%	
Patient 14	Venous 1	1.33	14%	3%
	Fingerstick 1	1.38	9%	
Patient 15	Venous 1	0.48	6%	-34%
	Fingerstick 1	0.36	15%	
Patient 16	Venous 1	1.62	18%	-6%
	Fingerstick 1	1.53	12%	
Patient 17	Venous 1	1.11	8%	32%
	Fingerstick 1	1.64	13%	
Patient 18	Venous 1	0.96	16%	-25%
	Fingerstick 1	0.77	6%	
Patient 19	Venous 1	1.74	12%	5%
	Fingerstick 1	1.82	10%	
Patient 20	Venous 1	1.89	5%	-3%
	Fingerstick 1	1.85	7%	

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8 ANTICOAGULANT COMPARISON

To test the effect of anticoagulants, 20 unique patients donated a total of 3 tubes, one EDTA, one Li Heparin, and one Serum. Calculated concentrations are based on the average RLU of 3 cartridges excluding outliers and dark count tips. The EDTA samples were tested using the predicate method and used in the Reference Range (3) experiments. As stated in section 3, Theranos results do not correlate with the predicate method results. This may be due to the sample type which is not an acceptable sample type for testing on the predicate method. The Theranos results of the matched samples correlated well.

Table 22: EDTA Plasma

Reported Value (uIU/mL)	All Tips		Dark Exclusion		Inter-Cartridge		Intra-Cartridge		Concentration			%CV	%Recovery
	Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip 1	Tip 2	Mean		
0.934	9125	9589	9125	9589	9357	4%	3723	7%	2.25	2.36	2.39	7%	256%
	9579	9985	9579	9985	9782	3%			2.35	2.45			
	9058	11002	9058	11002	10030	14%			2.23	2.68			
0.576	6572	5741	6572	5741	6157	10%	5195	17%	1.64	1.44	1.30	17%	226%
	4440	5414	4440	5414	4927	14%			1.11	1.36			
	4239	4766	4239	4766	4503	8%			1.06	1.20			
0.34	3719	4036	3719	4036	3878	8%	4249	18%	0.93	1.01	1.06	18%	313%
	3981	3386	3981	3386	3684	11%			0.90	0.84			
	5199	5175	5199	5175	5187	0%			1.30	1.30			
OORL	301	348	301	348	325	10%	279	15%	OORL	OORL	OORL	OORL	OORL
	252	267	252	267	260	4%			OORL	OORL			
	225	283	225	283	254	16%			OORL	OORL			
1.89	4100	20773	4100	20773	20773		17972	2%		4.86	4.24	11%	224%
	2181	18268	2181	18268	18268					4.31			
	16880	15966	16880	15966	16423	4%			4.00	3.80			
0.503	3837	4211	3837	4211	4024	7%	3943	6%	0.96	1.05	0.98	6%	196%
	4012	3740	4012	3740	3861	6%			1.00	0.92			
	5636	5786	5636	5786	5696	1%			1.41	1.44			
0.541	5600	5571	5600	5511	5556	1%	5680	3%	1.40	1.38	1.42	3%	263%
	5898	3	5898	DARK	5898				1.48				
	5188	5493	5188	5493	5341	4%			1.30	1.38			
0.526	4958	4786	4958	4786	4872	2%	5060	6%	1.24	1.20	1.27	6%	241%
	4687	5246	4687	5246	4967	8%			1.18	1.32			
	3699	59898	3699	59898									
0.885	10806	11682	10806	11682	11244	6%	11746	7%	2.64	2.84	2.85	6%	322%
	12673	11823	12673	11823	12248	5%			3.06	2.87			
	5616	17	5616	DARK	5616				1.41				
0.71	283	6839	283	6839	6839		6760	12%		1.71	1.69	11%	238%
	7310	7275	7310	7275	7293	0%			1.82	1.81			
	9729	9136	9729	9136	9433	4%			2.39	2.25			
0.987	8787	8916	8787	8916	8852	1%	8870	6%	2.17	2.20	2.19	6%	222%
	8611	8041	8611	8041	8326	5%			2.13	1.99			
	9722	9468	9722	9468	9595	2%			2.39	2.33			
0.823	7962	8825	7962	8825	8394	7%	9118	8%	1.98	2.18	2.25	8%	273%
	1800	9615	1800	9615	9615					2.36			
	4059	4431	4059	4431	4245	6%			1.01	1.11			
0.448	5934	5458	5934	5458	5696	6%	4897	14%	1.49	1.37	1.23	14%	274%
	4522	4975	4522	4975	4749	7%			1.13	1.25			



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0.445	4813	4895	4813	4895	4854	1%	5245	13%	1.21	1.23	1.32	13%	296%
	5707	6450	5707	6450	6079	9%			1.43	1.61			
	4973	4629	4973	4629	4801	5%			1.25	1.16			
0.896	13645	15072	13645	15072	14359	7%	12015	16%	3.28	3.60	2.91	15%	325%
	9752	11785	9752	11785	10769	13%			2.39	2.86			
	11019	10817	11019	10817	10918	1%			2.69	2.64			
0.626	6594	6321	6594	6321	6458	3%	6456	14%	1.65	1.58	1.61	14%	258%
	6714	5840	6714	5840	6277	10%			1.68	1.46			
	5285	7979	5285	7979	6632	29%			1.33	1.98			
0.512	4300	5025	4300	5025	4663	11%	5149	16%	1.08	1.26	1.29	16%	252%
	1264	6334		6334	6334				1.58	1.53			
	5573	4515	5573	4515	5044	15%			1.40	1.13			
0.618	7322	7704	7322	7704	7513	4%	6268	19%	1.82	1.91	1.57	18%	254%
	6914	5183	6914	5183	6049	20%			1.72	1.30			
	5413	5074	5413	5074	5244	5%			1.36	1.27			
0.339	3972	4125	3972	4125	4049	3%	3676	10%	0.99	1.03	0.91	10%	270%
	3241	3800	3241	3800	3521	11%			0.80	0.95			
	3592	3324	3592	3324	3458	5%			0.89	0.82			
0.655	7651	7646	7651	7646	7649	0%	7649	0%	1.90	1.90	1.90	0%	290%
	30	109	DARK	DARK									
	2	23	DARK	DARK									

Table 23: Li. Heparin Plasma

Reported Value (uIU/mL)	All Tips		Dark Exclusion		Inter-Cartridge		Intra-Cartridge		Concentration				
	Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip 1	Tip2	Mean	%CV	%Recovery
0.934	11723	11296	11723	11296	11510	3%	10312	15%	2.85	2.75	2.52	14%	270%
	8670	8664	8670	8664	8667	0%			2.14	2.14			
	11205	6	11205	DARK	11205				2.73				
0.576	5937	4628	5937	4628	5283	18%	5070	17%	1.49	1.16	1.27	17%	221%
	6152	5351	6152	5351	5752	10%			1.54	1.34			
	4278	4076	4278	4076	4177	3%			1.07	1.02			
0.34	3602	3	3602	DARK	3602		3938	8%	0.90		0.98	9%	289%
	4449	4024	4449	4024	4237	7%			1.11	1.01			
	3771	3843	3771	3843	3807	1%			0.94	0.96			
OORL	307	329	307	329	318	5%	363	11%	OORL	OORL	OORL	OORL	OORL
	384	371	384	371	378	2%			OORL	OORL			
	370	419	370	419	395	9%			OORL	OORL			
1.89	20532	21279	20532	21279	20906	3%	22168	8%	4.80	4.97	5.16	8%	273%
	21168	25510	21168	25510	23339	13%			4.94	5.89			
	21239	23280	21239	23280	22260	6%			4.96	5.40			
0.503	4106	5134	4106	5134	4620	16%	5068	16%	1.03	1.29	1.27	16%	253%
	4538	4653	4538	4653	4596	2%			1.14	1.17			
	5664	6315	5664	6315	5990	8%			1.42	1.58			
0.541	7451	6294	7451	6294	6873	12%	6560	13%	1.85	1.57	1.64	12%	303%
	5762	5496	5762	5496	5629	3%			1.44	1.38			
	7078	7278	7078	7278	7178	2%			1.76	1.81			
0.526	5492	5523	5492	5523	5508	0%	5508	3%	1.38	1.39	1.38	3%	263%
	5627	5792	5627	5792	5710	2%			1.41	1.45			
	5260	5353	5260	5353	5307	1%			1.32	1.34			



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0.885	15236	17055	15236	17055	16146	8%	12486	24%	3.64	4.04	3.02	22%	341%
	10854	11816	10854	11816	11335	6%			2.65	2.87			
	9417	10538	9417	10538	9978	8%			2.32	2.58			
0.71	7339	8084	7339	8084	7712	7%	8050	9%	1.83	2.00	2.00	8%	281%
	7401	7760	7401	7760	7581	3%			1.84	1.93			
	8696	9020	8696	9020	8858	3%			2.15	2.22			
0.987	9286	9572	9286	9572	9429	2%	10940	15%	2.29	2.35	2.67	14%	270%
	9983	11037	9983	11037	10510	7%			2.45	2.69			
	12750	13013	12750	13013	12882	1%			3.08	3.14			
0.823	7639	5652	7639	5652	6646	21%	8928	31%	1.99	1.43	2.20	29%	268%
	6309	10421	6309	10421	8365	35%			1.58	2.35			
	11333	12215	11333	12215	11774	5%			2.76	2.96			
0.448	5583	5660	5583	5660	5622	1%	6028	13%	1.30	1.42	1.51	12%	337%
	6949	7067	6949	7067	7008	1%			1.73	1.76			
	5563	5347	5563	5347	5455	3%			1.40	1.34			
0.445	4168	5343	4168	5343	4756	17%	7528	15%	1.04	1.34	1.33	15%	298%
	6229	6192	6229	6192	6211	0%			1.56	1.55			
	4848	4910	4848	4910	4879	1%			1.22	1.23			
0.896	204	11009		11009	11009		11023	10%		2.68	2.69	10%	300%
	9979	9802	9979	9802	9891	1%			2.45	2.41			
	12013	12310	12013	12310	12162	2%			2.91	2.98			
0.626	9157	8902	9157	8902	9030	2%	8355	11%	2.26	2.20	2.07	10%	330%
	6863	8631	6863	8631	7747	16%			1.71	2.13			
	2244	8212		8212	8212					2.03			
0.512	4886	5955	4886	5955	5421	14%	6514	15%	1.23	1.49	1.63	15%	318%
	6697	6596	6697	6596	6647	1%			1.67	1.65			
	7139	7811	7139	7811	7475	6%			1.78	1.94			
0.618			DARK	DARK			6319	7%			1.58	6%	256%
	5811	6378	5811	6378	6095	7%			1.46	1.60			
	6831	6257	6831	6257	6544	6%			1.71	1.57			
0.339	4263	4483	4263	4483	4373	4%	4262	5%	1.07	1.12	1.07	5%	315%
	4	38	DARK	DARK									
	3963	4339	3963	4339	4151	6%			0.99	1.09			
0.655	8257	8070	8257	8070	8164	2%	8496	17%	2.05	2.00	2.10	17%	321%
	10752	9730	10752	9730	10241	7%			2.62	2.39			
	6808	7361	6808	7361	7085	6%			1.70	1.83			



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Table 24: Serum

Reported Value (uIU/mL)	All Tips		Dark Exclusion		Inter-Cartridge		Intra-Cartridge		Concentration				%Recovery
	Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip 1	Tip 2	Mean	%CV	
0.934	7816	8239	7816	8239	8028	4%	10104	21%	1.94	2.04	2.48	20%	265%
	11929	12084	11929	12084	12007	1%			2.89	2.93			
	12156	8398	12156	8398	10277	26%			2.94	2.08			
0.576	5070	5845	5070	5845	5458	10%	6108	18%	1.27	1.46	1.53	18%	266%
	7902	7040	7902	7040	7471	8%			1.96	1.76			
	5292	5499	5292	5499	5396	3%			1.33	1.38			
0.34	3686	3702	3686	3702	3694	0%	3743	4%	0.92	0.92	0.93	4%	274%
	15	8	DARK	DARK					0.90	0.99			
	3632	3952	3632	3952	3792	6%							
OORL	167	337		337	337		334	5%	OORL	OORL	OORL	OORL	OORL
	316	339	316	339	328	5%			OORL	OORL			
	324	356	324	356	340	7%			OORL	OORL			
1.89	20820	22890	20820	22890	21855	7%	19529	12%	4.87	5.32	4.58	11%	242%
	17337	21044	17337	21044	19191	14%			4.10	4.92			
	17600	17482	17600	17482	17541	0%			4.16	4.13			
0.503	3451	4250	3451	4250	3851	15%	3905	11%	0.86	1.06	0.97	12%	194%
	3359	3736	3359	3736	3548	8%			0.83	0.93			
	4245	4386	4245	4386	4316	2%			1.06	1.10			
0.541	5277	5354	5277	5354	5316	1%	5608	6%	1.32	1.34	1.41	6%	260%
	6049	5	6049	DARK	6049				1.51				
	5462	5897	5462	5897	5680	5%			1.37	1.48			
0.526	4841	4788	4841	4788	4815	1%	5649	19%	1.21	1.20	1.42	18%	269%
	7426	5830	7426		7426				1.85				
	5518	5672	5518	5672	5595	2%			1.38	1.42			
0.885	8228	9092	8228	9092	8660	7%	8231	10%	2.04	2.24	2.04	9%	230%
	8421	7181	8421	7181	7801	11%			2.08	1.79			
	4	28	DARK	DARK									
0.71	6543	14	6543	DARK	6543		5867	25%	1.64		1.47	25%	207%
	3441	6985	3441	6985	5213	48%			0.85	1.74			
	5613	6753	5613	6753	6183	13%			1.41	1.69			
0.987	8852	9097	8852	9097	8975	2%	8724	19%	2.19	2.24	2.16	18%	218%
	6669	6905	6669	6905	6787	2%			1.67	1.72			
	10117	10703	10117	10703	10410	4%			2.48	2.61			
0.823	5019	8442	5019	8442	6731	36%	8978	23%	1.26	2.09	2.21	23%	269%
	10287	9838	10287	9838	10063	3%			2.52	2.41			
	10846	9436	10846	9436	10141	10%			2.65	2.32			
0.448	3586	4994	3586	4994	4290	23%	5138	22%	0.89	1.25	1.29	23%	288%
	37	38	DARK	DARK									
	5723	6247	5723	6247	5985	6%			1.43	1.56			
0.445	4473	4841	4473	4841	4657	6%	4795	6%	1.12	1.21	1.20	6%	270%
	4782	4685	4782	4685	4734	1%			1.20	1.17			


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0.896	4702	5287	4702	5287	4995	8%	9137	20%	1.18	1.33	2.25	19%	251%
	8106	7647	8106	7647	7877	4%			2.01	1.90			
	11472	7780	11472	7780	9626	27%			2.79	1.93			
	5438	10680		10680	10680				2.61				
0.626	6503	4392	6503	4392	5448	27%	5993	19%	1.63	1.10	1.59	13%	240%
	6033	9	6033	DARK	6033				1.51				
	7045	7	7045	DARK	7045				1.76				
0.512	5020	3560	5020	3560	4290	24%	4362	16%	1.26	0.88	1.09	16%	213%
	5043	4063	5043	4063	4553	15%			1.27	1.02			
	4819	3669	4819	3669	4244	19%			1.27	0.91			
0.618	5467	5063	5467	5063	5265	5%	5138	7%	1.37	1.27	1.29	7%	209%
	4494	5078	4494	5078	4786	9%			1.13	1.27			
	5276	5451	5276	5451	5364	2%			1.32	1.37			
0.339	3589	4	3589	DARK	3589		3553	14%	0.89		0.88	15%	260%
	3664	4090	3664	4090	3877	8%			0.91	1.02			
	1563	2868		2868	2868					0.70			
0.655	7450	7067	7450	7067	7259	4%	6352	17%	1.85	1.76	1.59	16%	243%
	235	149		DARK									
	5658	5232	5658	5232	5445	6%			1.42	1.31			

Table 25: EDTA v. Li Heparin v. Serum

Dark count tips were excluded in this summary as well as other major tip outliers highlighted in red.

Sample ID	EDTA Reported Value [uIU/mL]	Theranos Result [uIU/mL]		
		EDTA	Li Heparin	Serum
Patient 1	0.934	2.39	2.52	2.48
Patient 2	0.576	1.30	1.27	1.53
Patient 3	0.34	1.06	0.98	0.93
Patient 4	OORL	OORL	OORL	OORL
Patient 5	1.89	4.24	5.16	4.58
Patient 6	0.503	0.98	1.27	0.97
Patient 7	0.541	1.42	1.64	1.41
Patient 8	0.526	1.27	1.38	1.42
Patient 9	0.885	2.85	3.02	2.04
Patient 10	0.71	1.69	2.00	1.47
Patient 11	0.987	2.19	2.67	2.16
Patient 12	0.823	2.25	2.20	2.21
Patient 13	0.448	1.23	1.51	1.29
Patient 14	0.445	1.32	1.33	1.20
Patient 15	0.896	2.91	2.69	2.25
Patient 16	0.626	1.61	2.07	1.50
Patient 17	0.512	1.29	1.63	1.09
Patient 18	0.618	1.57	1.58	1.29
Patient 19	0.339	0.91	1.07	0.88
Patient 20	0.655	1.90	2.10	1.59

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Patient 4 was excluded from the figures 13, 14 and 15 because it was outside of the assay reportable range.

Figure 13: Theranos Results EDTA Plasma v Li Heparin Plasma

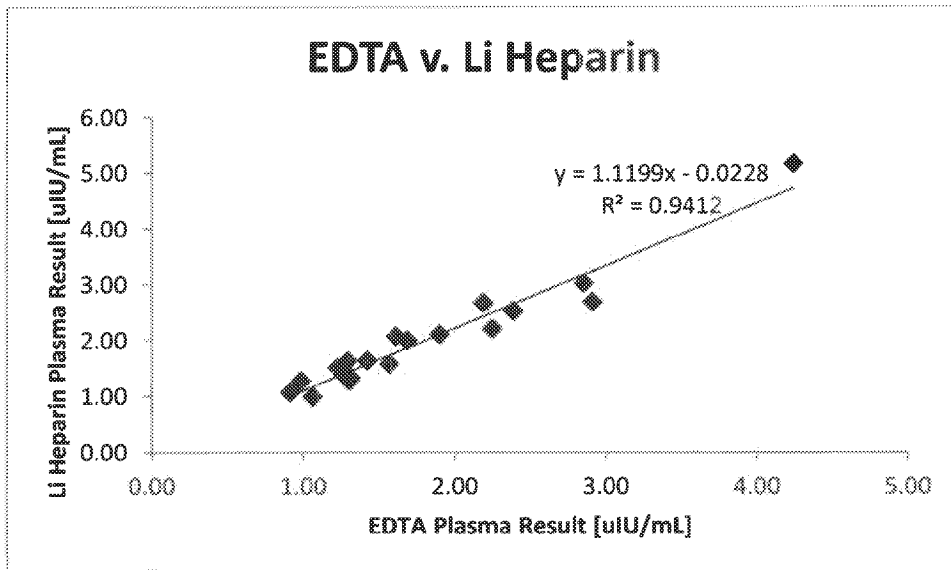
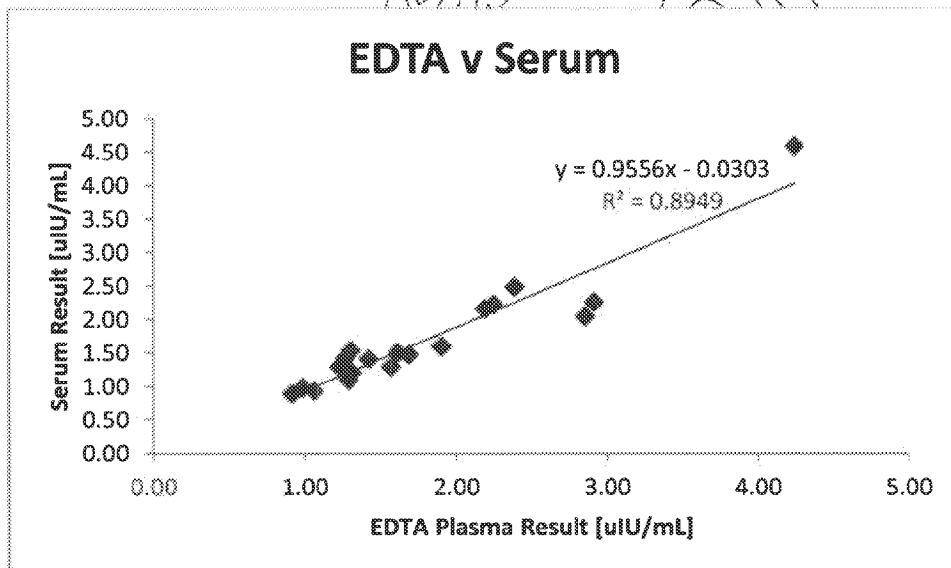


Figure 14: Theranos Results EDTA Plasma v Serum




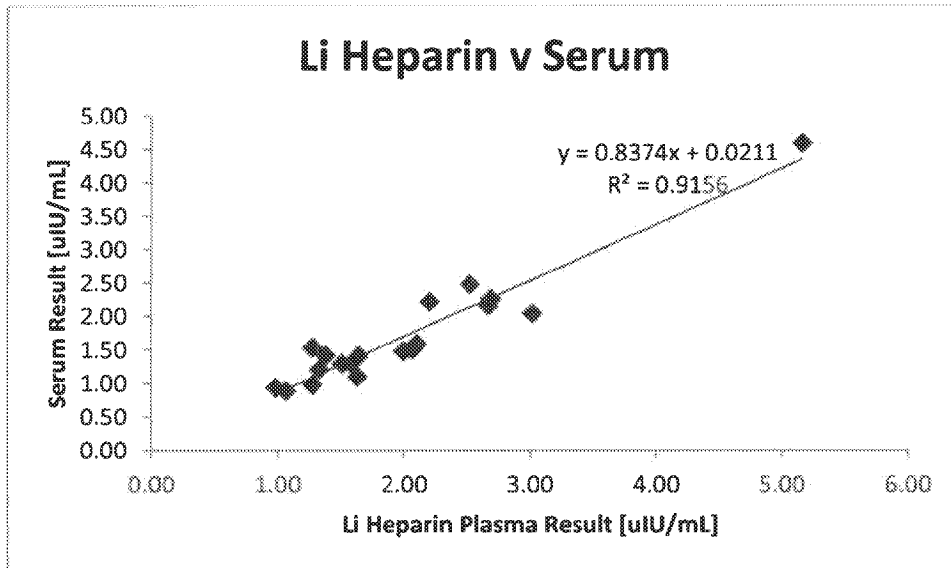
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Figure 15: Theranos Results Li Heparin Plasma v Serum



9 ANALYTICAL SENSITIVITY

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

After exclusion of dark count tips, 77 of the 116 tips are within the assay range and are reportable at the LLOQ. The Theranos test will report OORL in 34% of tests at the LLOQ.


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Table 26: LLOQ and 1/2LLOQ Preliminary Testing

LLOQ Level Sample				1/2 LLOQ Level Sample			
Intra-Cartridge		Mean RLU Calculated Result	Intra-Cartridge		Mean RLU Calculated Result		
Mean	%CV		Mean	%CV			
632	28%	0.09	415	37%	OORL		
RLU Tip1	RLU Tip2	Inter-Cartridge		RLU Tip1	RLU Tip2	Inter-Cartridge	
		Mean	%CV			Mean	%CV
779	873	826	8%	349	479	414	22%
709	603	656	11%	489	360	425	21%
792	548	670	26%	352	366	359	3%
660	490	575	21%	432	444	438	2%
666	619	643	5%	356	344	350	2%
572	574	573	0%	314	329	322	3%
617	5	311	139%	415	410	413	1%
497	544	521	6%	355	264	310	21%
856	886	871	2%	498	425	462	11%
644	773	709	13%	374	357	366	3%
596	516	556	10%	349	409	379	11%
636	751	694	12%	401	487	489	1%
384	607	496	32%	401	392	397	2%
499	368	434	21%	334	3	180	139%
497	534	516	8%	349	398	373	9%
813	657	735	15%	383	390	387	1%
579	904	742	31%	469	451	460	3%
739	921	830	16%	1053	894	974	12%
780	797	789	2%	462	459	461	0%
548	438	493	16%	350	361	356	2%



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Table 27: Blank and Lowest Detectable Sensitivity

Blank Level Sample						LLOQ Level Sample					
Intra-Cartridge		Mean RLU		Intra-Cartridge		Intra-Cartridge		Mean RLU		Intra-Cartridge	
Mean	%CV	Calculated Result		Mean	%CV	Mean	%CV	Calculated Result		Mean	%CV
195	39%	OORL		OORL	OORL	631	27%	0.09		0.11	19%
RLU Tip1	RLU Tip2	Inter-Cartridge		Dexter Calculated		RLU Tip1	RLU Tip2	Inter-Cartridge		Dexter Calculated	
		Mean	%CV	Tip 1	Tip 2			Mean	%CV	Tip 1	Tip 2
201	238	220	12%	OORL	OORL	779	873	826	8%	0.12	0.15
121	133	127	7%	OORL	OORL	709	603	656	11%	0.11	0.08
181	197	189	6%	OORL	OORL	792	548	670	26%	0.13	OORL
227	175	201	18%	OORL	OORL	660	490	575	21%	0.10	OORL
184	280	232	29%	OORL	OORL	666	619	642.5	5%	0.10	0.09
208	218	213	3%	OORL	OORL	372	574	573	0%	OORL	OORL
62	229	146	81%	OORL	OORL	617	5	311	139%	0.09	OORL
179	145	162	15%	OORL	OORL	497	544	520.5	6%	OORL	OORL
148	168	158	9%	OORL	OORL	856	886	871	2%	0.14	0.15
184	155	170	12%	OORL	OORL	644	773	708.5	13%	0.09	0.12
217	382	300	39%	OORL	OORL	596	516	536	10%	0.08	OORL
141	239	190	36%	OORL	OORL	636	751	693.5	12%	0.09	0.12
262	127	195	49%	OORL	OORL	384	607	495.5	32%	OORL	0.09
199	125	162	32%	OORL	OORL	499	368	433.5	21%	OORL	OORL
159	218	189	22%	OORL	OORL	497	634	515.5	5%	OORL	OORL
192	179	186	5%	OORL	OORL	813	657	735	15%	0.13	0.10
169	220	195	19%	OORL	OORL	579	904	741.5	31%	OORL	0.15
201	329	265	34%	OORL	OORL	739	921	830	16%	0.12	0.16
163	210	187	18%	OORL	OORL	780	797	788.5	2%	0.12	0.13
2	43	23	129%	OORL	OORL	548	438	493	16%	OORL	OORL
190	159	175	13%	OORL	OORL	492	721	606.5	27%	OORL	0.11
263	194	229	21%	OORL	OORL	460	404	432	9%	OORL	OORL
213	206	210	2%	OORL	OORL	686	695	690.5	1%	0.10	0.11
213	161	187	20%	OORL	OORL	640	764	702	12%	0.09	0.12
170	213	192	16%	OORL	OORL	724	8	366	138%	0.11	OORL
235	235	235	0%	OORL	OORL	793	827	810	3%	0.13	0.14
176	343	260	46%	OORL	OORL	454	504	479	7%	OORL	OORL
268	335	302	16%	OORL	OORL	996	671	833.5	28%	0.17	0.10
484	267	376	41%	OORL	OORL	884	662	773	20%	0.15	0.10
308	239	274	18%	OORL	OORL	Data Lost					
217	144	181	29%	OORL	OORL	624	734	679	11%	0.09	0.11
138	168	153	14%	OORL	OORL	600	656	628	6%	0.08	0.10
191	204	198	5%	OORL	OORL	550	746	648	21%	OORL	0.12
175	199	187	9%	OORL	OORL	661	572	616.5	10%	0.10	OORL
380	343	362	7%	OORL	OORL	614	722	668	11%	0.09	0.11
255	123	189	49%	OORL	OORL	807	852	829.5	4%	0.13	0.14
207	177	192	11%	OORL	OORL	579	615	597	4%	OORL	0.09
58	143	101	60%	OORL	OORL	741	638	689.5	11%	0.12	0.09
46	159	103	78%	OORL	OORL	703	678	690.5	3%	0.11	0.10



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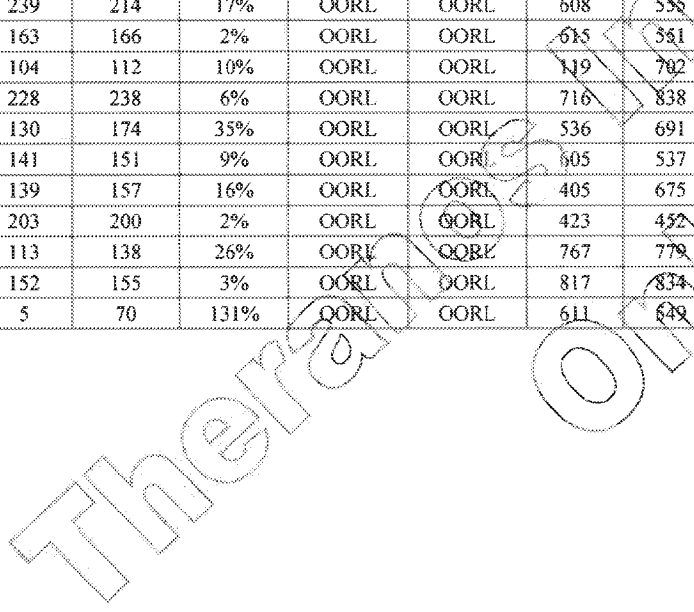
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Blank Level Sample (Continued)						LLOQ Level Sample (Continued)					
RLU Tip 1	RLU Tip 2	Mean	%CV	Calculated	Calculated	RLU Tip 1	RLU Tip 2	Mean	%CV	Calculated	Calculated
199	202	201	1%	OORL	OORL	594	666	630	8%	0.08	0.10
178	315	247	39%	OORL	OORL	930	791	860.5	11%	0.16	0.13
177	231	204	19%	OORL	OORL	773	694	733.5	8%	0.12	0.11
385	209	297	42%	OORL	OORL	639	564	601.5	9%	0.09	OORL
225	320	273	25%	OORL	OORL	694	594	644	11%	0.11	0.08
272	296	284	6%	OORL	OORL	570	326	448	39%	OORL	OORL
196	133	165	27%	OORL	OORL	598	506	552	12%	0.08	OORL
151	129	140	11%	OORL	OORL	558	471	514.5	12%	OORL	OORL
2	40	21	128%	OORL	OORL	225	672	448.5	70%	OORL	0.10
200	110	155	41%	OORL	OORL	729	726	727.5	0%	0.11	0.11
188	239	214	17%	OORL	OORL	608	555	581.5	6%	0.09	OORL
168	163	166	2%	OORL	OORL	615	581	583	8%	0.09	OORL
120	104	112	10%	OORL	OORL	719	702	410.5	100%	OORL	0.11
247	228	238	6%	OORL	OORL	716	838	777	11%	0.11	0.14
217	130	174	35%	OORL	OORL	536	691	613.5	18%	OORL	0.10
160	141	151	9%	OORL	OORL	605	537	571	8%	0.08	OORL
175	139	157	16%	OORL	OORL	405	675	540	35%	OORL	0.10
196	203	200	2%	OORL	OORL	423	452	437.5	5%	OORL	OORL
163	113	138	26%	OORL	OORL	767	779	773	1%	0.12	0.12
158	152	155	3%	OORL	OORL	817	834	825.5	1%	0.13	0.14
134	5	70	131%	OORL	OORL	611	629	580	8%	0.09	OORL



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10 INTERFERENCE

The recovery of analyte spiked into hemolyzed (270mg/dL Hemoglobin), icteric (20mg/dL Bilirubin), and lipemic (580mg/dL Triglycerides) serum samples was evaluated on the Theranos System and compared to predicate method values.

Nominal Recovery of the Interfering samples was acceptable when tested with 270 mg/dl of hemoglobin. Spike recovery of TSH from the icteric and lipemic samples was not within 20% especially at Level 1 and Level 3. The average recoveries were 96% and 107% respectively for the icteric and lipemic samples.


Table 28: Interfering Substances

Hemolyzed sample (hemoglobin 270mg/dL)										Dexter Calculated Result				
Sample ID	Reported Value (uIU/mL)	All Tips		Dark Exclusion		Inter-Cartridge		Intra-Cartridge		Concentration				
		Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip 1	Tip 2	Mean	%CV	%Recovery
Level 1	10.2	52475	53422	52475	53422	52949	1%	51539	4%	9.75	9.93	9.58	4%	94%
		52111	51362	52111	51362	51787	1%			9.88	9.54			
		23385	48325		48325	48325				8.97				
Level 2	7.3	30285	28125	30285	28125	29205	5%	31085	12%	5.83	5.24	5.78	11%	79%
		33986	34027	33986	34027	34007	0%			6.31	6.32			
		34294	25792	34294	25792	30043	20%			6.37	4.81			
Level 3	4.52	9442	21374		21374	21374		47513	15%		4.01	3.30	15%	73%
		14897	15133	14897	15133	15015	1%			2.83	2.87			
		17562	18598	17562	18598	18080	4%			3.31	3.50			
Level 4	1.08	5719	5856	5719	5856	5788	2%	5121	19%	1.12	1.14	1.00	19%	93%
		1319	5954		5954	5954				1.16				
		4025	4051	4025	4051	4038	0%			0.79	0.80			
Icteric sample (Bilirubin 20mg/dL)										Dexter Calculated Result				
Sample ID	Reported Value (uIU/mL)	All Tips		Dark Exclusion		Inter-Cartridge		Intra-Cartridge		Concentration				
		Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip 1	Tip 2	Mean	%CV	%Recovery
Level 1	6.11	60825	51313	60825	51313	56069	12%	54987	12%	11.35	9.53	10.23	12%	167%
		7909	61563		61563	61563				11.49				
		55219	46017	55219	46017	50618	13%			10.27	8.54			
Level 2	3.81	21990	14	21990	DARK	21990		16632	26%	4.12		3.14	25%	83%
		15767	17325	15767	17325	16546	7%			2.99	3.27			
		11447	5237	11447		11447				2.19				
Level 3	4.22	6797	5395	6797		6797		9328	18%	1.32		1.80	18%	43%
		2689	10228		10228	10228				1.97				
		9894	10392	9894	10392	10143	3%			1.90	2.00			
Level 4	0.997	1946	3864		3864	3864		4673	24%	0.76		0.92	24%	92%
		141	5481	DARK	5481	5481				1.07				
		21	53	DARK	DARK									

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Lipemic sample (Triglycerides 580mg/dL)										Dexter Calculated Result				
Sample ID	Reported Value (uIU/mL)	All Tips		Dark Exclusion		Inter-Cartridge		Intra-Cartridge		Concentration				
		Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip 1	Tip 2	Mean	%CV	%Recovery
Level 1	5.02	56078	3	56078	DARK	56078				10.44				
		39556	45609	39556	45609	42583	10%	47474	13%	7.34	8.46	8.81	13%	176%
		47073	49052	47073	49052	48063	3%			8.74	9.11			
Level 2	3.48	10313	8126	10313		10313				1.98				
		24219	21569	24219	21569	22894	8%	21354	30%	4.53	4.64	4.01	30%	115%
		23691	26976	23691	26976	25334	9%			4.43	5.03			
Level 3	3.66	1072	1064							1.78	0.64	1.15	44%	31%
		9113	3258	9113	3258	6186	67%	5880	45%	1.33	0.84			
		6853	4297	6853	4297	5575	32%			1.61	1.24			
Level 4	1.14	8301	6359	8301	6359	7330	19%			0.92	1.03	1.20	25%	105%
		4670	5254	4670	5254	4962	8%	8146	26%					
		6	6	DARK	DARK									

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11 CROSSREACTIVITY

Information about cross-reacting analytes from predicate method insert.

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

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


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

11.1.3 % cross-reactivity

The data showed that the Theranos TSH assay has 0.25% cross reactivity with LH.

Table 29: Cross-reactive Samples

Sample ID	All Tips		Dark Exclusion		Inter-Cartridge		Intra-Cartridge		Concentration				%Cross-reactivity
	Tip1	Tip2	Tip1	Tip2	Mean	%CV	Mean	%CV	Tip 1	Tip 2	Mean	%CV	
FSH 562.5 ng/mL (900 mIU/mL)	202	273	202	273	237.5	21%			OORL	OORL			
	133	135	133	135	134	1%	186	36%	OORL	OORL	OORL	OORL	OORL
	44	34	DARK	DARK									
LH 60 ng/mL	3152	750		750	750						0.12		
	899	844	899	844	871.5	4%	889	11%	0.15	0.14	0.15	15%	0.25%
	930	1020	930	1020	975	7%			0.16	0.18			
hCG 10,000 ng/mL	278	210	278	210	244	20%			OORL	OORL			
	209	213	209	213	211	1%	213	19%	OORL	OORL	OORL	OORL	OORL
	219	150	219	150	184.5	26%			OORL	OORL			

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12 SAMPLE STABILITY

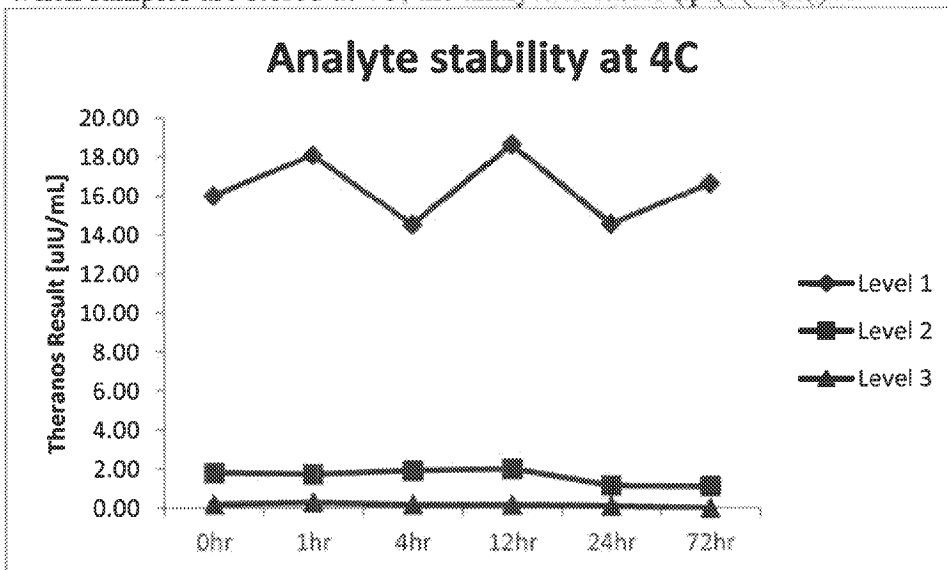
The stability of patient samples stored at 4C and room temperature were tested to mimic the conditions that clinical samples may be stored and handled.

Table 30: Sample Stability Summary

4C Results (uIU/mL)							Room Temperature (uIU/mL)						
Nominal	0hr	1hr	4hr	12hr	24hr	72hr	Nominal	0hr	1hr	4hr	12hr	24hr	72hr
20	15.99	18.08	14.53	18.61	14.55	16.62	20	15.99	18.38	15.33	17.74	18.12	16.51
2	1.81	1.73	1.90	2.00	1.14	1.10	2	1.81	1.26	1.64	1.34	1.19	1.23
0.2	0.19	0.28	0.17	0.16	0.11	OORL	0.2	0.19	0.19	0.14	0.12	0.17	OORL

Figure 16: 4C Sample Stability

When samples are stored at 4C, the analyte is stable up to 72 hours.




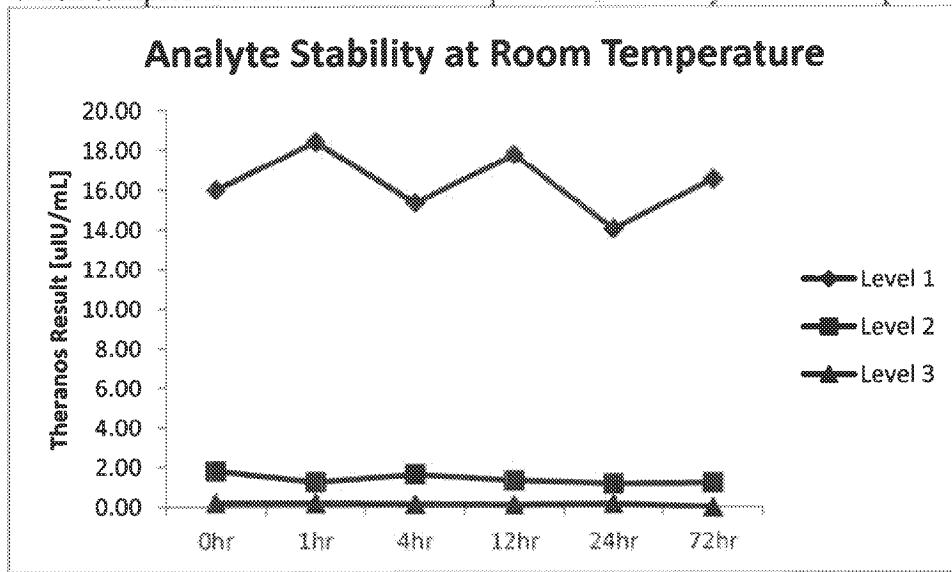
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Figure 17: Room Temperature Sample Stability

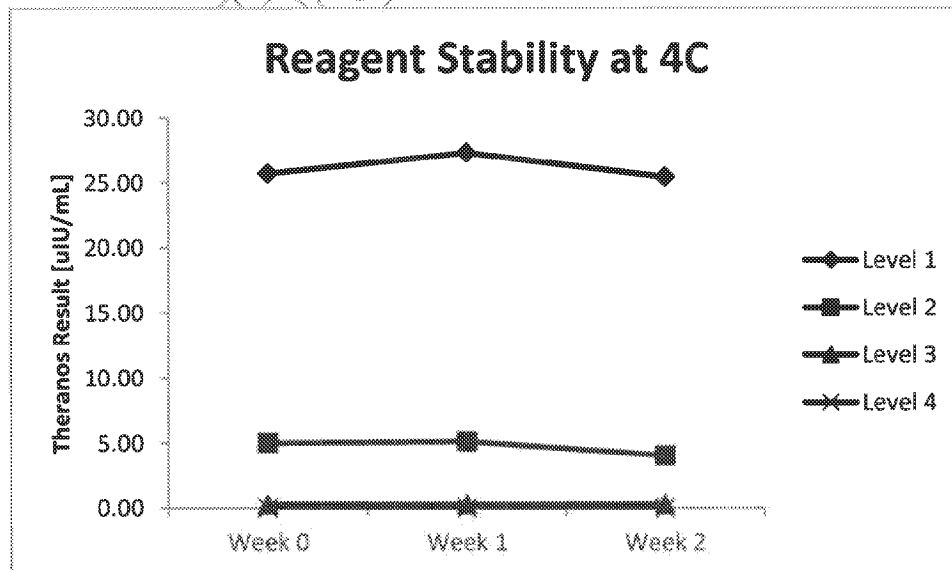
When samples are stored at room temperature, the analyte is stable up to 72 hours.




13 Reagent Stability

Reagent stability testing is ongoing. Reagents are stable up to 2 weeks.

Figure 18: Reagent Stability at 4C: 2 Weeks



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15 REFERENCES

- 15.1 Code of Federal Regulations, Title 42, Chapter IV, Subchapter G, Part 493, Subpart K, Sections 493.1217, 493.1253, and 493.1255.
- 15.2 DeSilva B, Smith W, Weiner R, et al. Recommendations for the bioanalytical method validation of ligand-binding assays to support pharmacokinetic assessments of macromolecules. *Pharmaceutical Res.* 2003; 20:1885-1900.
- 15.3 Guidance for Industry: bioanalytical method validation. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 2001.
- 15.4 R (version 2.13.1). The R Foundation for Statistical Computing, 07/08/2011.
- 15.5 StataPro (version 1.13.00). Clinical and Laboratory Standards Institute, Wayne, PA. 07/14/2011.
- 15.6 Dexter-Immunoassay (version 1.0), Theranos, Inc., 2009.
- 15.7 EP10-A3, Preliminary Evaluation of Quantitative Clinical Laboratory Measurement Procedures; Approved Guideline—Third Edition, 2006, Clinical and Laboratory Standards Institute, Wayne, PA.
- 15.8 EP15-A2, User Verification of Performance for Precision and Trueness; Approved Guideline—Second Edition, 2005, Clinical and Laboratory Standards Institute, Wayne, PA.
- 15.9 EP09-A2-IR, Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Second Edition (Interim Revision), 2010, Clinical and Laboratory Standards Institute, Wayne, PA.
- 15.10 EP05-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline—Second Edition, 2004, Clinical and Laboratory Standards Institute, Wayne, PA.
- 15.11 EP06-A, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline, 2003, Clinical and Laboratory Standards Institute, Wayne, PA.
- 15.12 EP7-A2, Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition, 2004, Clinical and Laboratory Standards Institute, Wayne, PA.