STUDY A

RAW DATA

SUBJECT	TSH CONCENTRATIONS (MIU/mL)		TOTAL T4 CONCENTRATIONS (ng/mL)					
	Screening	Pre-Dose	Pre-Dose Period 1			Pre-Dose Period 2		
1	3.3	2.8	90.883	89.369	86.728	83.291	87.782	86.877
2	1.5	1.6	104.55	107.015	107.553	104.400	106.287	106.098
3	1.6	3.1	98.093	100.885	101.240	147.351	110.744	116.595
4	0.7	0.8	93.625	94.448	108.200	99.411	112.116	96.573
5	1.7	2.9	87.810	89.820	87.293	89.180	85.407	83.297
6	2.3	1.7	62.234	68.853	67.199	71.027	65.198	67.199
7	2.0	2.1	71.838	73.711	76.552	88.977	85.893	84.751
8	2.5	3.6	65.395	66.773	66.219	79.797	74.408	76.465
9	1.2	2.7	99.608	97.099	101.429	91.165	84.317	83.882
10	0.8	0.8	97.913	100.441	100.815	97.287	97.691	95.079
11	1.7	2.4	87.111	84.209	86.305	100.207	90.113	92.876
12	1.1	1.2	62.301	63.638	59.108	57.758	57.003	57.662
13	1.9	2.9	169.859	133.998	173.462	121.410	107.097	110.817
14	2.2	1.8	105.648	89.577	131.294	86.510	91.803	96.065
15	1.6	1.5	Subject Withdrawn					
16	1.6	2.6	115.875	97.449	126.892	97.886	96.583	96.182
17	0.9	1.1	99.735	104.427	104.702	116.450	108.126	105.400
18	0.8	1.0	86.182	89.379	79.896	95.288	86.294	88.364
19	0.6	0.7	103.535	105.006	101.536	92.752	88.291	89.548
20	2.3	1.9	76.342	77.929	78.845	88.613	82.326	82.886
21	0.4	0.6	88.127	87.021	89.204	87.186	87.466	89.416
22	1.2	1.0	85.952	84.914	87.077	81.107	82.973	82.753
23	1.2	1.2	89.905	93.946	110.506	112.972	111.988	104.392
24	1.5	2.1	135.107	87.647	84.537	97.402	96.290	105.095
25	2.0	1.3	Alternate Subject					
26	1.9	1.4	102.397	99.988	114.927	86.946	81.497	95.602
27	1.3	1.6	Alternate Subject					
28	1.3	1.7	Alternate Subject					

STUDY A

TSH CALCULATION RESULTS

Subject	Variance Non-Transformed	LN (Screening)	LN (Pre-dose)	Variance LN Transformed
1	0.125	1.19392247	1.0296194	0.013498
2	0.005	0.40546511	0.4700036	0.002083
3	1.125	0.47000363	1.1314021	0.218724
4	0.005	-0.35667494	-0.223144	0.008915
5	0.72	0.53062825	1.0647107	0.142622
6	0.18	0.83290912	0.5306283	0.045687
7	0.005	0.69314718	0.7419373	0.00119
8	0.605	0.91629073	1.2809338	0.066482
9	1.125	0.18232156	0.9932518	0.328804
10	0	-0.22314355	-0.223144	0
11	0.245	0.53062825	0.8754687	0.059457
12	0.005	0.09531018	0.1823216	0.003785
13	0.5	0.64185389	1.0647107	0.089404
14	0.08	0.78845736	0.5877867	0.020134
15	0.005	0.47000363	0.4054651	0.002083
16	0.5	0.47000363	0.9555114	0.117859
17	0.02	-0.10536052	0.0953102	0.020134
18	0.02	-0.22314355	0	0.024897
19	0.005	-0.51082562	-0.356675	0.011881
20	0.08	0.83290912	0.6418539	0.018251
21	0.02	-0.91629073	-0.510826	0.082201
22	0.02	0.18232156	0	0.016621
23	0	0.18232156	0.1823216	0
24	0.18	0.40546511	0.7419373	0.056607
25	0.245	0.69314718	0.2623643	0.092787
26	0.125	0.64185389	0.3364722	0.046629
27	0.045	0.26236426	0.4700036	0.021557
28	0.08	0.26236426	0.5306283	0.035983
Average	0.216785714	0.33386618	0.473602	0.055296
			CV	0.23515

Sanford Bolton, Ph.D.

STUDY A

TOTAL T4 CALCULATION RESULTS
(Calculation of CV from the Range of 6 Readings)

Subject	Min.	Max.	LN Min	LN Max	Variance from LN (Range)	Variance from Range
1	83.291	90.88	4.422341	4.509539955	0.001184171	8.969244946
2	104.4	107.553	4.64823	4.677983749	0.000137873	1.548227297
3	98.093	147.351	4.585916	4.992817496	0.025784893	377.8681851
4	93.625	112.116	4.539297	4.71953405	0.005059094	53.24852425
5	83.297	89.82	4.422413	4.497807668	0.000885265	6.626459317
6	62.234	71.027	4.130901	4.263060086	0.002720055	12.04095478
7	71.838	88.977	4.274414	4.488377909	0.007129671	45.74648568
8	65.395	79.797	4.180446	4.37948591	0.006169756	32.30222159
9	83.882	101.429	4.429411	4.619359046	0.005618964	47.95043276
10	95.079	100.815	4.554708	4.613287154	0.000534406	5.123952136
11	84.209	100.207	4.433302	4.607238046	0.004711584	39.85824422
12	57.003	63.638	4.043104	4.153210776	0.00188806	6.855965655
13	107.097	173.462	4.673735	5.155958555	0.036214599	685.9065914
14	86.51	131.294	4.46026	4.877439083	0.027103901	312.3435494
16	96.182	126.892	4.566242	4.843336331	0.011957526	146.8745036
17	99.735	116.45	4.602517	4.757461996	0.003738899	43.5110477
18	79.896	95.288	4.380726	4.556903885	0.004833821	36.89579633
19	88.291	105.006	4.480638	4.654017491	0.00468146	43.5110477
20	76.342	88.613	4.335223	4.484278574	0.003460045	23.45020756
21	87.021	89.416	4.466149	4.493299637	0.000114797	0.893300988
22	81.107	87.077	4.395769	4.466792785	0.000785581	5.550542613
23	89.905	112.972	4.498754	4.72714	0.008123205	82.86459463
24	84.537	135.107	4.437189	4.906067057	0.034237814	398.2654992
26	81.497	114.927	4.400566	4.744297144	0.018400262	174.0441908
				Average Variance	0.008978154	108.0104071
				Average SD		10.39280554
				CV	0.094753123	0.111309863

The SD is estimated as the average range/2.534 (Pharmaceutical Statistics, Bolton and Bon, 4th Ed., Marcel Dekker, N.Y., Nov.2003)

Sanford Bolton, Ph.D.

STUDY A

TOTAL T4 CALCULATION RESULTS
(Calculation of CV from Random of 3 Readings, 2 Periods)

Data for Random Value Selection

Subject	Period 1 Low	Period 1 Mid	Period 1 High	Period 2 Low	Period 2 Mid	Period 2 High	Random Numbers	
	1	2	3	4	5	6		
1	86.728	89.369	90.883	83.291	86.877	87.782	0.626734	0.807134
2	104.55	107.015	107.553	104.4	106.098	106.287	0.744412	0.281387
3	98.093	100.885	101.24	110.744	116.595	147.351	0.081704	0.713652
4	93.625	94.448	108.2	96.573	99.411	112.116	0.072449	0.984536
5	87.293	87.81	89.82	83.297	85.407	89.18	0.734264	0.341797
6	62.234	67.199	68.853	65.198	67.199	71.027	0.418226	0.999982
7	71.838	73.711	76.552	84.751	85.893	88.977	0.610167	0.03331
8	65.395	66.219	66.773	74.408	76.465	79.797	0.665386	0.347137
9	97.099	99.608	101.429	83.882	84.317	91.165	0.962803	0.442833
10	97.913	100.441	100.815	95.079	97.287	97.691	0.901956	0.278098
11	84.209	86.305	87.111	90.113	92.876	100.207	0.321338	0.416215
12	59.108	62.301	63.638	57.003	57.662	57.758	0.073923	0.859887
13	133.998	169.859	173.462	107.097	110.817	121.41	0.210459	0.165286
14	89.577	105.648	131.294	86.51	91.803	96.065	0.132189	0.483038
16	97.449	115.875	126.892	96.182	96.583	97.886	0.438403	0.123235
17	99.735	104.427	104.702	105.4	108.126	116.45	0.762563	0.49793
18	79.896	86.182	89.379	86.294	88.364	95.288	0.339922	0.048121
19	101.536	103.535	105.006	88.291	89.548	92.752	0.584473	0.884211
20	76.342	77.929	78.845	82.326	82.886	88.613	0.322453	0.045179
21	87.021	88.127	89.204	87.186	87.466	89.416	0.021505	0.918221
22	84.914	85.952	87.077	81.107	82.753	82.973	0.412314	0.058734
23	89.905	93.946	110.506	104.392	111.988	112.972	0.547077	0.033435
24	84.537	87.647	135.107	96.29	97.402	105.095	0.056358	0.576707
26	99.988	102.397	114.927	81.497	86.946	95.602	0.706907	0.048121

Random numbers were used to choose one value from period 1 and one value from period 2. For example, for Subject1, readings were taken from column 6 (Period 2 High) and column 2 (Period 1 Mid).

Sanford Bolton, Ph.D.

STUDY A

TOTAL T4 CALCULATION RESULTS
(Calculation of CV from Random of 3 Readings, 2 Periods)

Final Calculations

Subject	(From Random Numbers)		Variance Non-Transformed	LN Period 1	LN Period 2	Variance LN Transformed
	Period 1	Period 2				
1	89.369	87.782	1.2592845	4.49277387	4.474856468	0.000160517
2	104.55	104.4	0.01125	4.64966543	4.648229675	1.03069E-06
3	98.903	110.744	70.1046405	4.59413957	4.707221231	0.006393731
4	94.448	96.573	2.2578125	4.54804942	4.570299199	0.000247526
5	89.82	83.297	21.2747645	4.49780767	4.422412534	0.002842213
6	62.234	65.198	4.392648	4.13090147	4.177428794	0.001082396
7	71.838	88.977	146.8726605	4.27441358	4.488377909	0.022890366
8	66.773	79.797	84.812288	4.20129881	4.37948591	0.015875322
9	99.608	91.165	35.6421245	4.60124248	4.512671051	0.003922449
10	97.913	97.287	0.195938	4.58407933	4.577665373	2.05694E-05
11	87.111	90.113	4.506002	4.46718317	4.501064438	0.00057397
12	63.638	57.662	17.856288	4.15321078	4.054598378	0.004862203
13	169.859	107.097	1969.534322	5.13496868	4.673734966	0.10636827
14	89.577	86.51	4.7032445	4.49509859	4.460260014	0.000606863
16	97.449	96.182	0.8026445	4.57932916	4.56624223	8.56339E-05
17	104.427	116.45	72.2762645	4.64848826	4.757461996	0.005937637
18	89.379	86.294	4.7586125	4.49288576	4.457760071	0.000616907
19	105.006	89.548	119.474882	4.65401749	4.494774794	0.012679118
20	78.845	82.326	6.0586805	4.3674839	4.410686975	0.000933253
21	88.127	87.466	0.2184605	4.47877896	4.471250146	2.83415E-05
22	84.914	81.107	7.2466245	4.44163898	4.395769271	0.001052015
23	110.506	111.988	1.098162	4.70506982	4.718391723	8.87366E-05
24	135.107	97.402	710.8335125	4.90606706	4.578846744	0.053536567
26	99.988	95.602	9.618498	4.60505018	4.56019374	0.00100605
Average	94.97454	91.29029	137.3254004	4.52931843	4.502486818	0.010075487
		SD	11.71859208		**CV**	0.100376725

Sanford Bolton, Ph.D.