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Assay Pre-Development Report
Hemoglobin
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[TOC \o "1-4" \f \h \z]

1. Assay Specifications[TC "Assay Specifications" \f C \l "1"]

This assay is designed to detect hemoglobin in human whole blood. The assay has a reportable range of 2.5 – 18.0 g/dL.

2. Reference Assays[TC "Reference Assays" \f C \l "1"]

The Teco Hemoglobin Reagent Set Cat # H526480 was used as a reference method.

3. Reagent Formulation[TC "Reagent Formulation" \f C \l "1"]

Assay Reagents

Name	Supplier	Cat #	Conc/fw	Storage	Form
Drabkin's reagent (Contains sodium bicarbonate, potassium ferricyanide, and potassium cyanide.)	Sigma	D5941	n/a	Room Temp, Dark	Lyophilized
Brij 35 solution, C12E23, Polyoxyethylene (23) lauryl ether	Sigma	B4184	30 % (w/v)	Room Temp	Liquid
Hemoglobin, bovine	Sigma	H2500		4C	Powder

Stock Solutions

Reconsitute Drabkin's reagent with 100mL DD H_2O to create a 10X stock solution. Store at room temp in an opaque container, stable > 2 years.

Hb Working Reagent (Reagent A)

Component	Initial Conc	Volume (mL)	Final Conc in Reagent	Final Conc with Sample
Drabkin's reagent	10 X	74.66	1.493 X	0.996 X
Brij 35	30 %	0.37	0.022 %	0.015 %
Water		424.96		
Total Volume		500.00		

Calibrators

Dissolve Sigma Hemoglobin in DD H_2O at 18 g/dL. Create a serial dilution in water as shown below. Verify the concentration in the Teco Hb kit. Calibrators are stable stored at 4C for 1 year. Aliquot in sealed vials to avoid evaporation and contamination. Do not freeze.

Calibrator #	[Hb] g/dL
1	18.0
2	16.0
3	14.0
4	12.0
5	10.0
6	5.0
7	2.5
8	0

Serial dilution

Units: g/dL, uL

	Previous/Stock	Required Final			Diluent	
	Conc.	Conc.	Total Volume	Add	Volume	Type
1		18.0	5000			Water
2	18	16.0	4200	3733.3	466.7	Water
3	16	14.0	3600	3150.0	450.0	Water
4	14	12.0	3200	2742.9	457.1	Water
5	12	10.0	3000	2500.0	500.0	Water
6	10	5.0	2000	1000.0	1000.0	Water
7	5	2.5	1200	600.0	600.0	Water
8	3	0.0	1000	0.0	1000.0	Water

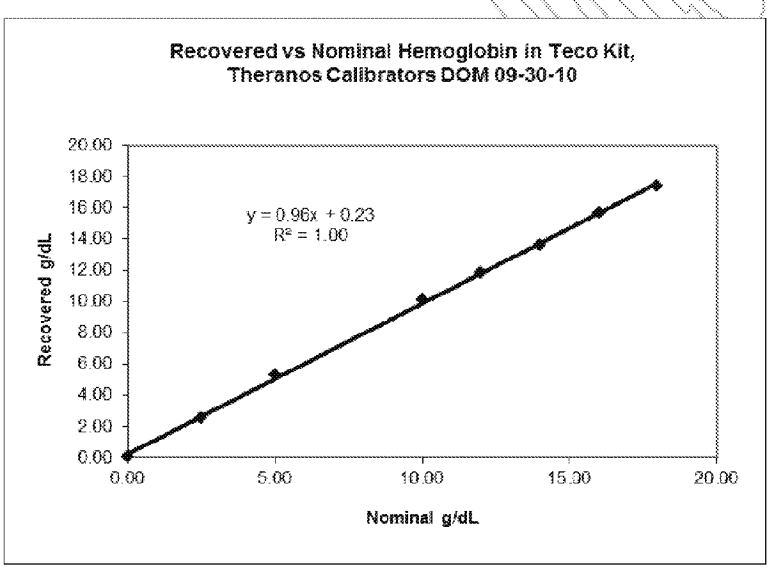
4. Calibrator Verification[TC "Calibrator Verification" \f C \l "1"]

The Theranos calibrators were verified in the Teco Hemoglobin Kit.

Results:

- Theranos calibrators were accurately recovered.

Theranos Calibrators Batch 1 DOM 09-30-10 run as samples on kit						
Calibrator #	[Nominal] g/dL	Mean OD	Std.Dev.	CV%	Calc.	% Recovery
1	18.00	0.445	0.012	2.7	17.43	97
2	16.00	0.401	0.018	4.6	15.70	98
3	14.00	0.347	0.017	4.9	13.59	97
4	12.00	0.302	0.005	1.6	11.83	99
5	10.00	0.258	0.008	3.1	10.10	101
6	5.00	0.135	0.004	2.8	5.29	106
7	2.50	0.065	0.001	2.3	2.55	102
8	0.00	0.001	0.002	191.3	0.04	



5. Chemistry Formulation

Reagent A was prepared as specified, and whole blood samples were diluted 1:100 into water to achieve lysis by osmotic pressure, then further diluted 1:3 into Reagent A. Therefore final sample dilution was 1:300. The sample mixtures were placed in a 96 well clear-bottom MTP and incubated at 37C for 10 minutes and then the absorbance read at 540 nm. The plate was further incubated at 37C and read again at 30 minutes to ensure that the reaction had reached endpoint at 10 minutes.

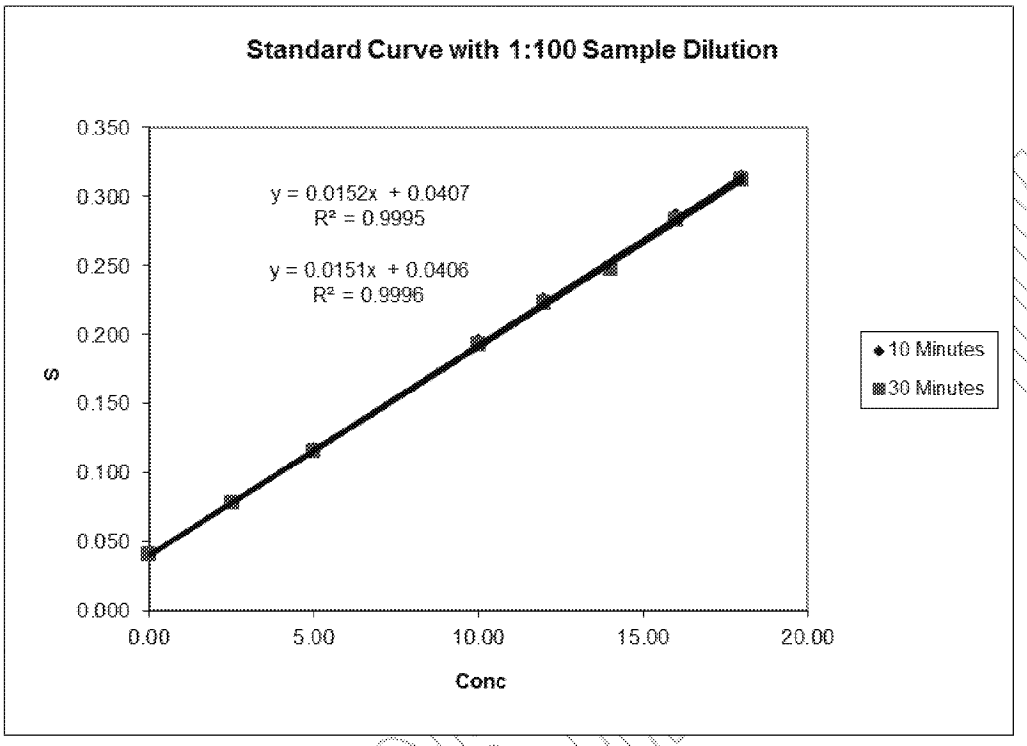
Results: the assay had reached an endpoint by 10 minutes and a longer incubation was not necessary.

MTP Read at 10 Min

Standard Curve					Back-Calculated Conc., g/dL			
[Hb] g/dL	OD	Mean OD	Std.Dev.	CV%	Conc g/dL	Mean Conc	CV %	% Recovery
18.00	0.312	0.314	0.004	1.2	17.85	18.01	1.3	100
	0.317				18.18			
16.00	0.285	0.286	0.001	0.2	16.07	16.11	0.3	101
	0.286				16.14			
14.00	0.250	0.249	0.001	0.3	13.77	13.74	0.3	98
	0.249				13.70			
12.00	0.225	0.225	0.000	0.2	12.13	12.13	0.0	101
	0.225				12.13			
10.00	0.194	0.195	0.001	0.7	10.09	10.15	0.9	102
	0.196				10.22			
5.00	0.116	0.116	0.001	0.5	4.95	4.99	0.9	100
	0.117				5.02			
2.50	0.079	0.078	0.000	0.1	2.52	2.49	1.9	99
	0.078				2.45			
0.00	0.041	0.041	0.000	0.5	0.02	0.02	0.0	
	0.041				0.02			
S/B		7.7						
Avg Concentration CV %							0.7	

MTP Read at 30 Minutes

Standard Curve					Back-Calculated Conc., g/dL			
[Hb] g/dL	OD	Mean OD	Std.Dev.	CV%	Conc g/dL	Mean Conc	CV %	% Recovery
18.00	0.309	0.312	0.004	1.2	17.77	17.94	1.3	100
	0.314				18.11			
16.00	0.283	0.283	0.000	0	16.05	16.05	0.0	100
	0.283				16.05			
14.00	0.247	0.247	0.001	0.4	13.67	13.64	0.3	97
	0.246				13.60			
12.00	0.222	0.223	0.000	0.1	12.01	12.05	0.4	100
	0.223				12.08			
10.00	0.192	0.193	0.002	0.8	10.03	10.09	0.9	101
	0.194				10.16			
5.00	0.114	0.115	0.001	0.6	4.86	4.89	1.0	98
	0.115				4.93			
2.50	0.078	0.078	0.000	0.1	2.48	2.48	0.0	99
	0.078				2.48			
0.00	0.041	0.041	0.000	0.7	0.03	0.03	0.0	
	0.041				0.03			
S/B		7.6						
Avg Concentration CV %							0.5	



Sample Dilution[TC "Sample Dilution" \f C \l "1"]

Three sample predilutions were tested to optimize assay response and sample utilization 1:30, 1:100 and 1:300. All samples were further diluted 1:3 into Reagent A. A set of whole blood samples and controls were run in addition to the standard curve to ensure that ideal sample dilution was determined by whole blood Hb recovery.

Results:

- The 1:30 sample dilution provided the best modulation and recovery of whole blood samples.

Effect of Sample Dilution, Standard Curve

Sample Predilution	[Hb] g/dL	Signal, OD		Back-Calc Conc, g/dL		
		Mean OD	CV%	Mean Conc	CV %	% Recovery
30x	18.00	0.870	3.8	17.76	4.0	99
	16.00	0.789	1.6	16.02	1.8	100
	14.00	0.709	0.9	14.29	1.0	102
	12.00	0.601	2.9	11.95	3.2	100
	10.00	0.514	0.2	10.05	0.2	100
	5.00	0.289	1.1	5.20	1.5	104
	2.50	0.164	0.6	2.47	0.6	99
	0.00	0.041	0.5	-0.18	0.0	
100x	18.00	0.299	1.8	17.99	1.9	100
	16.00	0.270	0.9	15.93	1.2	100
	14.00	0.241	1.2	13.90	1.4	99
	12.00	0.215	1.3	12.08	1.6	101
	10.00	0.189	0.7	10.27	1.0	103
	5.00	0.113	0.2	4.99	1.0	100
	2.50	0.078	0.2	2.50	0.0	100
	0.00	0.041	1.2	-0.08	0.0	
300x	18.00	0.124	0.5	17.50	0.8	97
	16.00	0.117	0.4	15.94	0.0	100
	14.00	0.111	2	14.79	3.0	106
	12.00	0.097	1.7	11.88	3.7	99
	10.00	0.086	1.3	9.48	3.1	95
	5.00	0.064	3.6	4.79	9.2	96
	2.50	0.052	0.3	2.40	0.0	96
	0.00	0.041	0.7	0.10	0.0	

Effect of Sample Dilution, Whole Blood Results and Control Recovery

Sample predilution	Sample #	Reported [Hb] g/dL	Signal, OD Mean OD	CV%	Conc, g/dL Mean Conc	CV %	% Recovery
30x	1		0.742	1.8	14.99	2.0	N/A
	2		0.817	2.1	16.62	2.2	N/A
	3		0.835	1.9	17.01	2.0	N/A
	4		0.728	0.9	14.70	0.9	N/A
	5		0.758	1.7	15.34	1.8	N/A
	6		0.740	1.0	14.95	1.0	N/A
	7		0.799	1.9	16.22	2.0	N/A
	8		0.785	0.3	15.91	0.3	N/A
	Teco CTL 1	6.7	0.393	0.4	7.43	0.6	111
	Teco CTL 2	13.5	0.737	0.2	14.87	0.1	110
	Teco CTL 3	17.5	0.873	0.5	17.82	0.6	102
100x	1		0.260	0.1	15.20	0.3	N/A
	2		0.281	0.6	16.73	0.9	N/A
	3		0.279	1.3	16.59	1.5	N/A
	4		0.256	0.1	14.95	0.0	N/A
	5		0.247	0.3	14.36	0.3	N/A
	6		0.233	2.0	13.34	2.2	N/A
	7		0.267	0.4	15.69	0.3	N/A
	8		0.262	0.1	15.37	0.0	N/A
	Teco CTL 1	6.7	0.151	-	7.61	-	114
	Teco CTL 2	13.5	0.262	2.9	15.41	3.5	114
	Teco CTL 3	17.5	0.312	4.8	18.87	5.8	108
300x	1		0.110	1.0	14.48	2.0	N/A
	2		0.122	1.1	16.98	1.7	N/A
	3		0.118	1.2	16.15	1.8	N/A
	4		0.107	1.0	13.85	2.1	N/A
	5		0.109	1.5	14.27	2.1	N/A
	6		0.099	0.2	12.29	1.2	N/A
	7		0.117	0.2	16.04	0.9	N/A
	8		0.115	1.9	15.52	3.8	N/A
	Teco CTL 1	6.7	0.079	0.1	8.02	0.0	120
	Teco CTL 2	13.5	0.127	0.9	18.13	0.8	134
	Teco CTL 3	17.5	0.132	2.8	18.96	3.9	108

6. Reagent Titration[TC "Reagent Titration" \f C \l "1"]

To determine if a lower concentration of Drabkin's reagent is effective with the 1:90 final sample dilution, the assay was run with Reagent A consisting a 1:2 and a 1:10 dilution of the Drabkin's reagent into water. Three whole blood control samples were run in addition to the standard curve. All reagent concentrations showed excellent dose response and recovery of control samples. On the spectrophotometer, the 1:2 dilution of Drabkin's reagent showed the best signal to background. However, pilot tests on the Theranos system showed a drop in modulation with the diluted reagent and therefore the original 1x concentration was retained for the duration of predevelopment. Further optimization should be done on the Theranos platform once it is characterized.

Titration of Drabkin's Reagent

		[Hb] g/dL	Signal Mean OD	CV%	Back-Calculated Conc., g/dL Mean Conc	CV %	% Recovery
1x Control		18.00	0.965	1.2	18.19	1.2	101
		16.00	0.862	1.0	16.21	1.0	101
		14.00	0.735	1.0	13.78	1.0	98
		12.00	0.624	1.0	11.66	1.0	97
		10.00	0.529	1.6	9.82	1.7	98
		5.00	0.296	1.8	5.35	2.0	107
		2.50	0.166	0.6	2.87	0.5	115
		0.00	0.041		0.46		
	Teco CTL 1	6.7	0.414	0.6	7.62	0.7	114
	Teco CTL 2	13.5	0.787	0.2	14.78	0.2	109
	Teco CTL 3	17.5	1.053	1.5	19.88	1.5	114
1:2 Dilution		18.00	1.130	0.9	18.64	1.0	104
		16.00	0.989	2.6	16.31	2.7	102
		14.00	0.839	3.2	13.81	3.2	99
		12.00	0.710	0.2	11.67	0.2	97
		10.00	0.556	1.2	9.13	1.2	91
		5.00	0.293	0.2	4.75	0.2	95
		2.50	0.164	1.3	2.61	1.3	104
		0.00	0.041	0.3	0.57	2.0	
	Teco CTL 1	6.7	0.406	2.9	6.63	3.0	99
	Teco CTL 2	13.5	0.773	1.2	12.73	1.2	94
	Teco CTL 3	17.5	1.038	2.4	17.12	2.4	98
1:10 Dilution		18.00	0.978	1.1	17.84	1.2	99
		16.00	0.881	4.3	15.97	4.6	100
		14.00	0.777	1.9	13.97	2.1	100
		12.00	0.680	0.7	12.09	0.8	101
		10.00	0.581	1.1	10.20	1.2	102
		5.00	0.321	0.1	5.18	0.0	104
		2.50	0.182	2.2	2.50	3.3	100
		0.00	0.040	0	-0.24	0.0	
	Teco CTL 1	6.7	0.392	0	6.54	0.2	98
	Teco CTL 2	13.5	0.769	1	13.80	1.1	102
	Teco CTL 3	17.5	1.019	0.8	18.64	0.8	107

7. Accuracy and Precision[TC "Accuracy and Precision" \f C \l "1"]

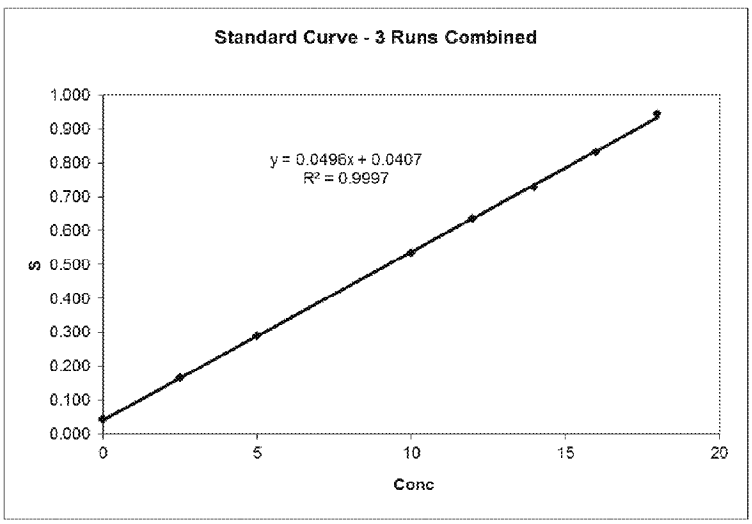
The assay was run 3 times with a standard curve and 3 whole blood samples and 3 lyophilized whole blood control samples obtained from Teco.

Results:

- Combining all 3 standard curves results in an average back-calculated concentration CV of 1.6% across the range for the standard curve.
- Calculating the concentration CV of the whole blood samples based on the combined 3 run standard curve resulted in an average concentration CV of 2.3 %.

Standard Curve 3 Runs, Signal (OD)

Conc g/dL	Run 1 OD	Mean OD	CV%	Run 2 OD	Mean OD	CV%	Run 3 OD	Mean OD	CV%	3 Run Mean Mean OD	CV%
18	0.951	0.955	0.5	0.936	0.939	0.5	0.941	0.944	0.4	0.946	0.8
	0.958			0.942			0.947				
16	0.832	0.828	0.6	0.814	0.813	0.2	0.848	0.850	0.4	0.831	2.1
	0.824			0.812			0.853				
14	0.723	0.730	1.3	0.700	0.720	4.0	0.732	0.738	1.3	0.730	2.2
	0.737			0.741			0.745				
12	0.626	0.631	1.1	0.619	0.628	2.1	0.643	0.643	0.1	0.634	1.5
	0.637			0.638			0.643				
10	0.537	0.537	0.1	0.516	0.530	3.7	0.540	0.539	0.2	0.535	1.8
	0.537			0.543			0.538				
5	0.291	0.290	0.6	0.289	0.289	0.0	0.289	0.287	1.1	0.288	0.8
	0.288			0.289			0.284				
2.5	0.166	0.166	0.1	0.165	0.166	1.0	0.166	0.168	1.6	0.167	1.1
	0.166			0.167			0.170				
0	0.044	0.042		0.041	0.041		0.049	0.046		0.043	
	0.041			0.041			0.043				



Standard Curve 3 Runs, Back-Calculated Concentration (g/dL)

Back-Calculated Concentrations				
Run 1	**Run 2**	**Run 3**	**Mean Conc**	**CV%**
18.4	18.1	18.2	18.2	0.9
18.5	18.2	18.3		
16.0	15.6	16.3	15.9	2.2
15.8	15.6	16.4		
13.8	13.3	13.9	13.9	2.4
14.0	14.1	14.2		
11.8	11.7	12.1	12.0	1.6
12.0	12.0	12.1		
10.0	9.6	10.1	10.0	2.0
10.0	10.1	10.0		
5.0	5.0	5.0	5.0	0.9
5.0	5.0	4.9		
2.5	2.5	2.5	2.5	1.4
2.5	2.5	2.6		
0.1	0.0	0.2	0.0	
0.0	0.0	0.0		
Avg Concentration CV %				**1.6**

Recovery of Whole Blood Samples, Signal (OD)

		Run 1			Run 2			Run 3		
Sample #	**[Hb] g/dL**	**OD**	**Mean OD**	**CV%**	**OD**	**Mean OD**	**CV%**	**OD**	**Mean OD**	**CV%**
2		0.758	0.766	1.6	0.764	0.771	1.3	0.751	0.743	1.5
		0.775			0.778			0.735		
3		0.693	0.697	1.0	0.694	0.697	0.5	0.748	0.741	1.4
		0.702			0.700			0.734		
4		0.520	0.525	1.4	0.518	0.523	1.1	0.559	0.556	0.7
		0.531			0.527			0.553		
Teco CTL 1	6.7	0.399	0.403	1.3	0.404	0.404	0.2	0.400	0.404	1.2
		0.407			0.403			0.408		
Teco CTL 2	13.5	0.756	0.759	0.5	0.771	0.769	0.3	0.802	0.799	0.4
		0.762			0.767			0.797		
Teco CTL 3	17.5	1.011	1.008	0.4	1.000	0.996	0.5	0.977	0.984	1.0
		1.006			0.993			0.991		

Recovery of Whole Blood Samples, Concentration (g/dL)

Sample #	[Hb] g/dL	Calculated Concentrations Run 1	Run 2	Run 3	Mean Conc	CV%	% Recovery
2		14.5	14.6	14.3	14.5	2.2	n/a
		14.8	14.9	14.0			
3		13.2	13.2	14.3	13.5	3.5	n/a
		13.3	13.3	14.0			
4		9.7	9.6	10.4	10.0	3.5	n/a
		9.9	9.8	10.3			
Teco CTL 1	6.7	7.2	7.3	7.2	7.3	1.0	109
		7.4	7.3	7.4			
Teco CTL 2	13.5	14.4	14.7	15.3	14.8	2.6	110
		14.5	14.6	15.2			
Teco CTL 3	17.5	19.6	19.3	18.9	19.3	1.3	110
		19.5	19.2	19.2			
Avg CV %						2.3	

8. Clinical Correlation and Hematocrit Correlation[TC "Clinical Correlation" \f C \l "1"]

A set of 18 normal whole blood samples were obtained. In order to create a range of Hb, each sample was either diluted into it's own plasma or spiked with its own RBC prepared from a separate aliquot. The unaltered sampels and the adjusted samples were then tested in the Teco kit and the Theranos assay. The hematocrit was determined using hematocrit tubes and a hematocrit centrifuge. HCT under 15 are estimates because these levels are out of range low.

A: Unadulterated samples
B: Dilutions of A samples in own plasma or spiked with RBC to create more range in samples

		Hematocrit %	
Tube #	**Blood Type**	**A**	**B**
1	B+	44	39
2	O-	48	38
3	A-	41	27
4	AB+	38	24
5	O+	48	26
6	O+	44	16
7	O+	51	14
8	A+	54	10
9	O+	54	5
10	O+	49	43
11	O+	45	60
12	AB+	46	31
13	A+	63	73
14	O+	58	28
15	O+	53	69
16	A+	49	12
17	AB-	40	5
18	B+	47	1

Results:

- Correlation of the Theranos results to the Teco kit results was excellent. Correlation of the Theranos Hb result to the measured hematocrit was also excellent.

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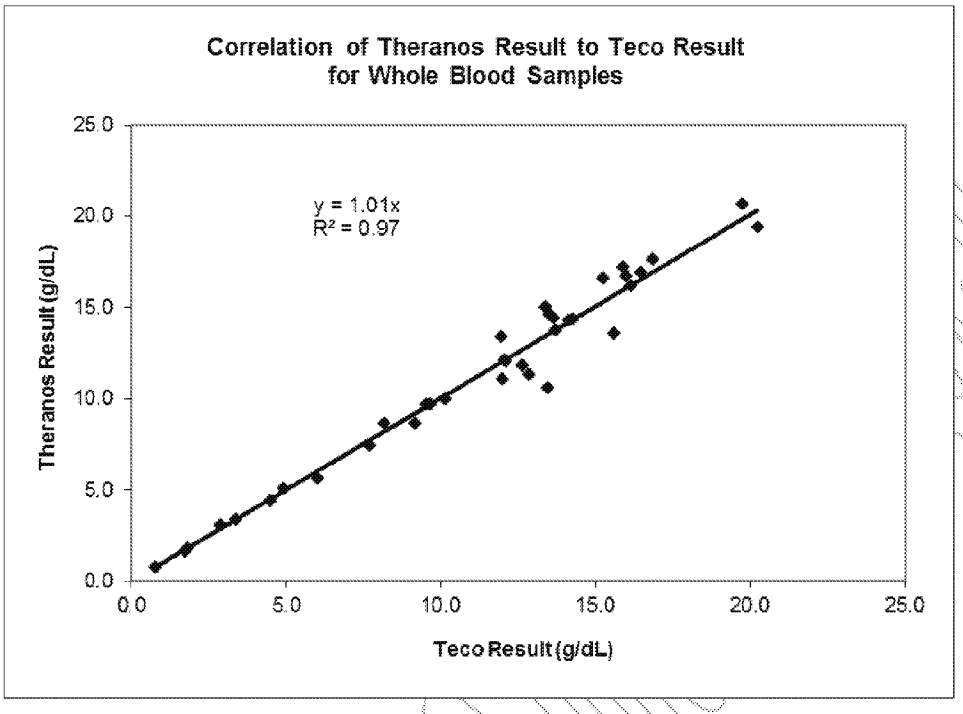
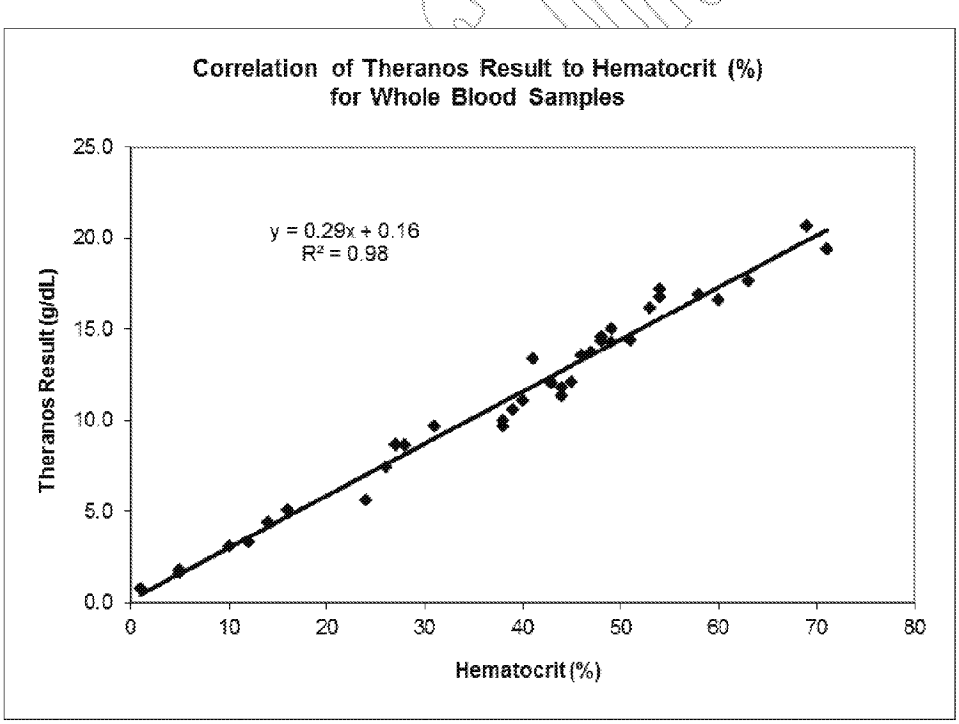
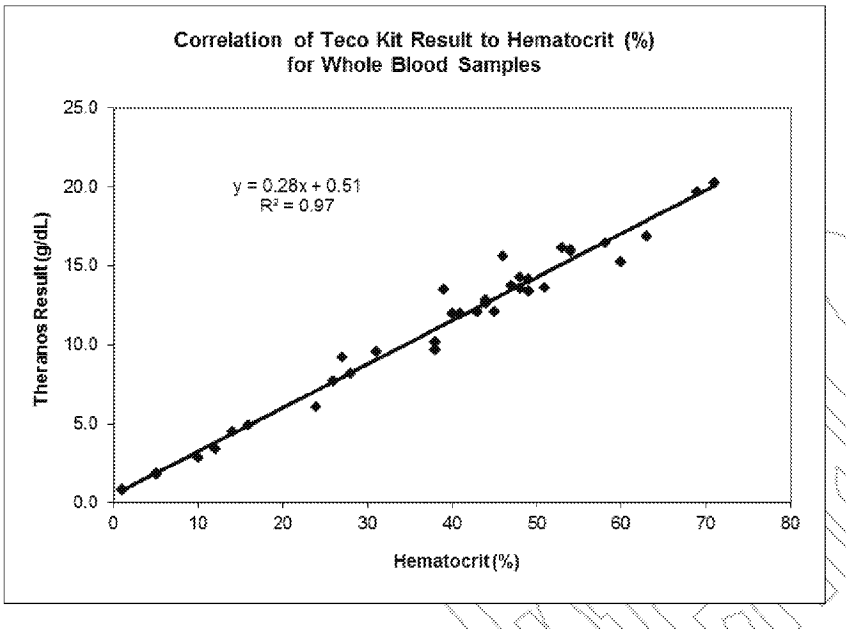
Clinical Samples Hemoglobin Result (g/dL)

Set	Sample#	HC %	Teco Result (g/dL) Mean Conc	Teco Result (g/dL) CV %	Theranos Result (g/dL) Mean Conc	Theranos Result (g/dL) CV %
A	1	44	12.8	7.5	11.3	0.6
	2	48	14.3	3.7	14.4	2.1
	3	41	12.0	0.9	13.4	2.7
	4	38	9.7	0.6	9.7	1.5
	5	48	13.5	3.7	14.6	1.5
	6	44	12.6	1.7	11.8	0.8
	7	51	13.6	2.4	14.4	0.3
	8	54	15.9	6.6	17.2	4.4
	9	54	16.0	2.9	16.7	1.9
	10	49	13.4	1.0	15.0	3.9
	11	45	12.1	0.9	12.1	0.1
	12	46	15.6	1.9	13.6	2.5
	13	63	16.9	4.1	17.6	2.3
	14	58	16.5	1.5	16.9	1.5
	15	53	16.1	9.7	16.2	2.0
	16	49	14.1	8.4	14.3	0.7
	17	40	12.0	2.5	11.1	0.1
	18	47	13.7	8.0	13.7	3.7
B	1	39	13.5	1.4	10.6	9.0
	2	38	10.1	4.6	10.0	5.8
	3	27	9.2	0.9	8.6	9.2
	4	24	6.0	2.7	5.6	6.9
	5	26	7.7	-	7.4	2.2
	6	16	4.9	2.2	5.1	1.0
	7	14	4.5	3.1	4.4	1.2
	8	10	2.9	1.9	3.1	1.7
	9	5	1.8	6.3	1.6	0.8
	10	43	12.1	5.2	12.1	2.5
	11	60	15.2	4.0	16.6	0.5
	12	31	9.5	2.9	9.7	4.3
	13	71	20.2	5.6	19.4	1.7
	14	28	8.2	2.4	8.6	0.3
	15	69	19.7	2.4	20.7	0.3
	16	12	3.4	6.5	3.3	0.4
	17	5	1.8	0.0	1.8	0.7
	18	1	0.8	10.3	0.8	3.4


Correlation of Theranos Result to Teco Result
for Whole Blood Samples
y = 1.01x
R² = 0.97
Theranos Result (g/dL)
Teco Result (g/dL)
0.0
5.0
10.0
15.0
20.0
25.0


Correlation of Theranos Result to Hematocrit (%)
for Whole Blood Samples
y = 0.29x + 0.16
R² = 0.98
Theranos Result (g/dL)
Hematocrit (%)
0.0
5.0
10.0
15.0
20.0
25.0
0
10
20
30
40
50
60
70
80



9. Dilution Linearity[TC " Dilution Linearity " \f C \l "1"]

Dilution linearity was tested by dividing a whole blood sample into 2 aliquots, spinning down one aliquot and taking the RBC from pellet and spiking the RBC back in to the untouched whole blood to increase Hb concentration, then doing serial dilution into the plasma. The serial dilution was done with a dilution ratio: 164 uL previous + 36uL plasma, this rartio was used to calculate the nominal concentration using the formula Nominal = (Previous*164 + 0 * 36)/(200).

Results:

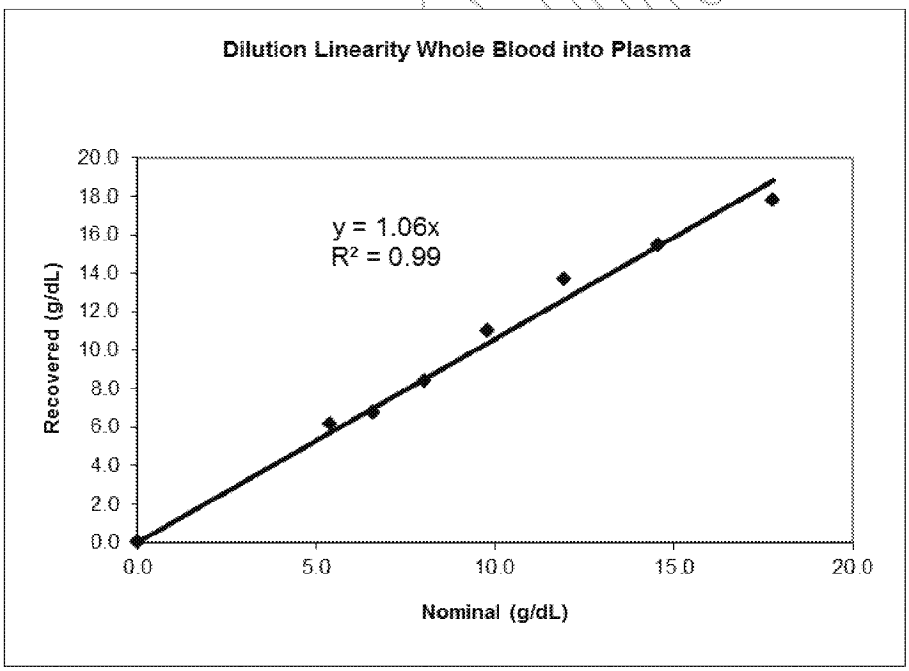
- Dilution linearity was maintained across the range.

Standard Curve

Conc	Signal (OD)			Back-Calculated Conc, g/dL			
g/dL	OD	Mean OD	CV%	Conc g/dL	Mean Conc	CV %	% Recovery
18	0.951	0.955	0.5	18.3	18.3	0.5	102
	0.958			18.4			
16	0.832	0.828	0.6	15.9	15.8	0.7	99
	0.824			15.7			
14	0.723	0.730	1.3	13.7	13.8	1.4	99
	0.737			14.0			
12	0.626	0.631	1.1	11.8	11.9	1.3	99
	0.637			12.0			
10	0.537	0.537	0.1	10.0	10.0	0.0	100
	0.537			10.0			
5	0.291	0.290	0.6	5.0	5.0	0.8	100
	0.288			5.0			
2.5	0.166	0.166	0.1	2.5	2.5	0.0	101
	0.166			2.5			
0	0.044	0.042		OORL	OORL	-	-
	0.041			OORL			

Dilution Linearity

[Nominal] mg/dL	Signal, OD			Calibration Verification			
	OD	Mean OD	CV%	Conc g/dL	Mean Conc	CV %	% Recovery
17.8	0.930	0.926	0.6	17.8	17.8	0.6	100
	0.922			17.7			
14.6	0.818	0.809	1.7	15.6	15.4	1.7	106
	0.799			15.2			
11.9	0.730	0.720	1.9	13.8	13.6	2.0	114
	0.711			13.5			
9.8	0.592	0.587	1.1	11.1	11.0	1.2	112
	0.583			10.9			
8.0	0.454	0.457	1.0	8.3	8.4	1.0	104
	0.460			8.4			
6.6	0.378	0.377	0.2	6.8	6.8	0.2	103
	0.377			6.8			
5.4	0.351	0.347	1.6	6.2	6.2	1.8	114
	0.343			6.1			
0.0	0.042	0.042	0.8	OORL	OORL	-	-
	0.042			OORL			



10. Interference[TC "Interference" \f C \l "1"]

Interference due to icteric, lipemic or hemolyzed samples was tested by taking 2 O-Negative blood samples spinning them down, removing the plasma and resuspending in an equal volume of:

1. Control - RBC resuspended and then serially diluted in original plasma
2. Lipemic - RBC resuspended and then serially diluted in ProMedDx Lipemic Serum (severely lipemic)
3. Icteric - RBC resuspended and then serially diluted in ProMedDx Icteric Serum (severely icteric)

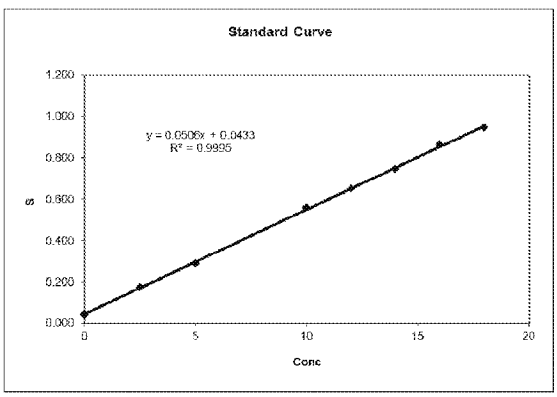
After resuspension, the samples were diluted serially into the test matrix. Nominal concentration is based on the control samples.

Results:

- Severely lipemic samples with concurrent abnormally low Hb may be over-estimated.
- Icteric samples are accurately measured across the range.

Standard Curve

[Hb] g/dL	OD	Mean OD	CV%	Back-Calculated Conc, g/dL Conc g/dL	Mean Conc	CV %	% Recovery
18	0.938	0.946	1.2	17.68	17.83	1.2	99
	0.953			17.98			
16	0.867	0.864	0.4	16.28	16.23	0.4	101
	0.862			16.18			
14	0.741	0.748	1.4	13.79	13.94	1.5	100
	0.756			14.08			
12	0.652	0.651	0.2	12.03	12.01	0.2	100
	0.650			11.99			
10	0.563	0.559	1.0	10.27	10.19	1.1	102
	0.555			10.11			
5	0.292	0.289	1.2	4.92	4.87	1.4	97
	0.287			4.82			
2.5	0.177	0.173	3.7	2.64	2.55	4.9	102
	0.168			2.46			
0	0.044	0.042	4.4	OORL	OORL		
	0.041			OORL			



Interfering Matrixes

			Signal (OD)			Concentration g/dL			
Sample #	Matrix	Nominal	OD	Mean OD	CV%	Conc g/dL	Mean Conc	CV %	% Recovery
2	Control	12.1	0.660	0.656	0.8	12.2	12.1	0.9	100
			0.652			12.0			
		6.4	0.400	0.398	0.8	7.0	7.0	0.8	109
			0.396			7.0			
		3.4	0.212	0.212	0.1	3.3	3.3	0.0	98
			0.212			3.3			
	Icteric	12.1	0.658	0.654	0.8	12.1	12.1	0.8	100
			0.651			12.0			
		6.4	0.405	0.402	0.9	7.1	7.1	1.0	111
			0.400			7.0			
		3.4	0.237	0.236	0.4	3.8	3.8	0.7	112
			0.235			3.8			
	Lipemic	12.1	0.696	0.691	1.1	12.9	12.8	1.2	106
			0.685			12.7			
		6.4	0.441	0.440	0.4	7.9	7.8	0.4	122
			0.439			7.8			
		3.4	0.282	0.279	1.4	4.7	4.7	1.8	137
			0.276			4.6			
3	Control	12.6	0.679	0.681	0.5	12.6	12.6	0.6	100
			0.684			12.7			
		6.7	0.414	0.412	0.8	7.3	7.3	1.0	109
			0.409			7.2			
		3.5	0.217	0.217	0.2	3.4	3.4	0.0	97
			0.217			3.4			
	Icteric	12.6	0.687	0.682	0.8	12.7	12.6	1.0	100
			0.678			12.5			
		6.7	0.366	0.365	0.6	6.4	6.3	0.7	95
			0.363			6.3			
		3.5	0.219	0.219	0.4	3.5	3.5	0.4	98
			0.218			3.5			
	Lipemic	12.6	0.698	0.690	1.8	12.9	12.8	1.9	101
			0.681			12.6			
		6.7	0.405	0.406	0.3	7.1	7.2	0.4	107
			0.407			7.2			
		3.5	0.286	0.280	3.1	4.8	4.7	3.6	132
			0.274			4.6			