To: Daniel Edlin[dedlin@theranos.com]
From: Elizabeth Holmes
Sent: Sun 6/1/2014 12:11:10 AM
Importance: Normal
Subject: RE: Roger Parloff - aggregated action items
Received: Sun 6/1/2014 12:11:11 AM
Theranos Multiplexed Panel Validation Report_Schering Plough.pdf

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From: Elizabeth Holmes
Sent: Saturday, May 31, 2014 5:09 PM
To: Daniel Edlin
Subject: RE: Roger Parloff - aggregated action items

From: Elizabeth Holmes
Sent: Friday, May 30, 2014 6:07 PM
To: Daniel Edlin
Subject: RE: Roger Parloff - aggregated action items

What can be disclosed is devices

Decentralizable

Will decentralize

Will maintain centralized oversight

From: Daniel Edlin
Sent: Tuesday, May 27, 2014 9:54 PM
To: Elizabeth Holmes
Cc: Jeffrey Blickman; Christian Holmes
Subject: RE: Roger Parloff - aggregated action items

Hi Elizabeth,

Please see below/attached for the Roger Parloff action items list. This does not take into account the photo shoot with Fortune mag. The item numbers have also stayed the same so it's easier to keep track of each task.

Please let me know if you have any questions.

#	Action Item	Resource
STILL NEED TO GIVE TO ROGER - OPEN		
3	Our lab form – showing the reflex testing configuration we will release in the future/all future features	Daniel Y
4	Sepsis paper that will be published	Daniel Y
5	Background on the fact that we figured out how to freeze capillary blood	Daniel Y
6	Data on amount of blood required to do additional tests using a traditional sample that could do any possible reflex tests vs. Theranos - Calculate the number of draws that would be required	Daniel Y
7	Data on performance of POC instruments not being as accurate/good	Daniel Y
8	Data on any combination of tests being able to be done on our framework	Daniel Y
10	Follow up on our finger stick being less painful than a traditional lancet b/c it's a narrower and less deep lancet	Daniel Y / PM Tea

11	Follow up on the DARPA – CAP article and confidentiality - Follow up on IP associated with CLIA lab permitted to have hardware outside its premises	EAH
12	Language on what he can say about our having devices, and how many devices we are using in each facility - How many analyzers per sample he's allowed to talk about - Being able to work within a smaller space – language on this	EAH
13	Follow up on what he's allowed to disclose with respect to software and POC machines being controlled by a certified lab	EAH
15	Language on when our first revenue was	EAH
16	Language on why we do some venipuncture	EAH
17	Language on the device comparison and lab comparison b/t Theranos and Quest	EAH
18	Language on medical advisory board	EAH
19	Point about the fact that we're a CLIA certified lab and not a technology company that publishes on our technology – background on this	EAH
22	Follow up on intermountain POC - How far along we are and operationalizing that in terms of their sending us samples	EAH and PM Tear
33	Patent application figures - EAH as co-inventor Are the following figures, listing EAH as a co-inventor, up to date? - 80 US patent applications; including - 17 issued US patents; and - 2 'allowed' US patents. - 182 foreign applications; including - 65 issued patents; and - 4 'allowed' patents.	IP Team (who on
34	Patent application figures - EAH NOT LISTED as co-inventor - How many US Patent applications? - How many issued US patents? - How many 'allowed' US patents? - How many foreign applications? - How many foreign issued patents? - How many foreign 'allowed' patents?	IP Team (who on
35	Patent application figures - general - Has Theranos supplemented its portfolio with patents purchased from other sources? - Can you say or estimate the size of Theranos's entire patent portfolio from all sources?	IP Team (who on
36	Physician contacts Roger can talk to	EAH
37	Speaking to Medicare/Medicaid	EAH
38	Lab report showing trending data	Jeff/Daniel
39	Follow up on operationalizing the infectious disease tests with Helfet	EAH
40	Possible PT data, validation reports, pharma reports, and valuation	EAH Thoughts
STILL NEED TO GIVE TO ROGER - IN PROGRESS		
1	Follow up on all of our state certifications	Adam/Mark/Brad
21	Quotes from pharma companies	EAH / Previous pr
23	Data on how far along we are with Dignity	EAH and PM Tear
30	Medicare/Medicaid sources on savings from reflex testing	PM team
32	More quotes from patients, physicians, nurses, payors (LIST FROM SALES)	SALES

DONE - SENT TO ROGER		
20	Send him the Moira Gunn interview	EAH / PM Team
26	IPad App – show mock up	Jeff
27	Preview of .md and .me – consumer focus	Jeff
28	Recording of HEP presentation	PM Team
31	More quotes from patients (LIST FROM RYAN)	PM - RYAN
DONE - PER EAH		
2	Data – showing our performance vs. hospital labs (or other labs)	Daniel Y
9	Follow up on Vitamin D CV and NIST / CDC standards being less than 5%	Daniel Y
14	Follow up as to what year Larry Ellison invested	EAH
25	Is it OK to talk to General Mattis?	EAH or Dan
29	Include data on the fact that we're making pricing at 90% below Medicare (chlamydia and gonorrhea)	PM team
NO LONGER NEEDED		
24	Intro to Charles Roussel	EAH or Dan

Thanks,

Dan

From: Christian Holmes
Sent: Thursday, May 22, 2014 8:47 PM
To: Elizabeth Holmes
Cc: Jeffrey Blickman; Daniel Edlin
Subject: Re: Roger Parloff - aggregated action items

Elizabeth – please see notes below and attachments for PM action items. In addition to the quotes from pharma diligence, I have the binder as well. I am keeping this locked in the cabinet next to my desk (I have the key so it's secure).

Let us know if there are questions.

Thanks

Christian

20: Send him the Moira Gunn interview

- Attached
- URL: http://web.archive.org/web/20130729223151id_/http://itc.conversationsnetwork.org/series/technation.html?series=&chann

21: Quotes from pharma companies

- GSK: After running clinical trials with Theranos instead of the central laboratory, GlaxoSmithKline's Lab Director concluded that "Theranos' lab infrastructure eliminates the need for a lab." (*see more below for full quote)*
- Johns Hopkins: "The technology is novel and sound. It can accurately run a wide range of routine and special assays." "No major weaknesses were identified."
- I also pulled the binder of pharma due diligence. Particular areas of relevance:
    - Pfizer-TheranosAngiogenesis Study Report: p. 26 lists conclusions of study

- "The Theranos System performed with superior performance to reference assays while running in a complex ambulatory environment."

- "One of Theranos' pharma partner is publishing a report which estimates the increased time to market is valued at $1M per day – making every month quite substantial."

- "Based on historical data, implementation of these systems will enable Pfizer to achieve ~50% cost savings over current study spending (previously demonstrated to be $15M of a $30M study budget."

- Schering-Plough-Theranos Assay Validation Report: p. 14 lists conclusions of study.

  - "The Theranos IL-6, TNF-alpha, CRP assay multiplex has been shown to give more accurate and precise results for three independently calibrated cartridge lots and all the many instruments used than current "gold standard" reference methods."

- Excerpts from GSK-Theranos Metabolic Study Report:

  - "The Theranos system eliminate the need for a lab and provided quality data"

  - "The Metabolic Biomarker Lab has a favorable impression of the technology/system and recommends GSK clinical groups to work with Theranos"

22: Follow up on intermountain POC. How far along we are and operationalizing that in terms of their sending us samples

- Roger already reached out to George, who is standing by to hear from us before engaging back with Roger. With regard to status, we have a kickoff meeting scheduled for next week to iron out logistics for sending samples.

23: Data on how far along we are with Dignity

- Waiting on approval of the list of who the point people are internally to get this in motion, along with approval of the list that Daniel sent for phase 1 validation. In parallel we are working with their IT people on EMR integration with the next meeting scheduled for May 28

26: IPad App – show mock up

- Attached

27: Preview of .md and .me – consumer focus

- Attached

28: Recording of HEP presentation

- We emailed Julie to ask for clips or a copy of the session. Waiting on this, but she said probably not until the end of the month. Here is the URL for your speaker page: http://www.healthevolutionpartners.com/elizabeth-holmes/

29: Include data on the fact that we're making pricing at 90% below Medicare (chlamydia and gonorrhea)

- For chlamydia and gonnorhea test (panel) we are about half off of CMS rates, per what's on our website. Checked with Sunny per our discussion and he said to use the flu panel as an example for infectious disease in this case. Our pricing below is 50% Medicare

87633		Resp virus 12-25 targets	$572.91	$286.46

30: Medicare/Medicaid sources on savings from reflex testing

- CMS

- Henry J Kaiser Family Foundation (kff.org)
- Medicaid.gov
- Theranos pricing

31: More quotes from patients, physicians, nurses, payors

- Attached email entitled "Aggregate List of Customer Feedback"

From: Daniel Edlin
Sent: Wednesday, May 21, 2014 5:26 AM
To: Elizabeth Holmes
Cc: Christian Holmes; Jeffrey Blickman
Subject: Roger Parloff - aggregated action items

Hi Elizabeth,

Please see below for the updated, aggregated list of follow-up items for Roger Parloff. I've also included a column for a suggested contact person/resource for each item. If you have any guidance on when we may need these items by, or if there is someone else we should be reaching out to, please let us know and we'll communicate accordingly to the resources. As per emails from yesterday, we're in process of compiling the updated quotes (#31).

#	Action Item	Resourc
1	Follow up on all of our state certifications	Adam/M
2	Data – showing our performance vs. hospital labs (or other labs)	Daniel Y
3	Our lab form – showing the reflex testing configuration we will release in the future/all future features	Daniel Y
4	Sepsis paper that will be published	Daniel Y
5	Background on the fact that we figured out how to freeze capillary blood	Daniel Y
6	Data on amount of blood required to do additional tests using a traditional sample that could do any possible reflex tests vs. Theranos - Calculate the number of draws that would be required	Daniel Y
7	Data on performance of POC instruments not being as accurate/good	Daniel Y
8	Data on any combination of tests being able to be done on our framework	Daniel Y
9	Follow up on Vitamin D CV and NIST / CDC standards being less than 5%	Daniel Y
10	Follow up on our finger stick being less painful than a traditional lancet b/c it's a narrower and less deep lancet	Daniel Y
11	Follow up on the DARPA – CAP article and confidentiality - Follow up on IP associated with CLIA lab permitted to have hardware outside its premises	EAH
12	Language on what he can say about our having devices, and how many devices we are using in each facility - How many analyzers per sample he's allowed to talk about - Being able to work within a smaller space – language on this	EAH
13	Follow up on what he's allowed to disclose with respect to software and POC machines being controlled by a certified lab	EAH
14	Follow up as to what year Larry Ellison invested	EAH
15	Language on when our first revenue was	EAH
16	Language on why we do some venipuncture	EAH
17	Language on the device comparison and lab comparison b/t Theranos and Quest	EAH
18	Language on medical advisory board	EAH
19	Point about the fact that we're a CLIA certified lab and not a technology company that publishes on our technology – background on this	EAH

20	Send him the Moira Gunn interview	EAH / Pl
21	Quotes from pharma companies	EAH / Pr present
22	Follow up on intermountain POC - How far along we are and operationalizing that in terms of their sending us samples	EAH and
23	Data on how far along we are with Dignity	EAH and
24	Intro to Charles Roussel	EAH or I
25	Is it OK to talk to General Mattis?	EAH or I
26	IPad App – show mock up	Jeff
27	Preview of .md and .me – consumer focus	Jeff
28	Recording of HEP presentation	PM Tear
29	Include data on the fact that we're making pricing at 90% below Medicare (chlamydia and gonorrhea)	PM tear
30	Medicare/Medicaid sources on savings from reflex testing	PM tear
31	More quotes from patients, physicians, nurses, payors	PM/Sale

I've also attached the ppt deck previously sent to Roger, for reference.

Thanks,

Dan

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Schering Corporation
Schering Plough Research Institure
Assay Development Report
Theranos Systems Multiplexed Human IL-6, Human TNF-α, Human CRP (hs)

Contents

1. Introduction
2. Storage and Use
3. Calibration
4. Range
5. Quantitation Limits and Accuracy
6. Precision
7. Specificity
8. Linearity
9. Matrix Effects
10. Stability

1. Introduction

The Theranos Assay System is a fully automated means for measuring concentrations of analytes (biomarkers, drugs) using immunoassay methodology. The system is comprised of instruments, single-use cartridges and a wireless communications link that conveys protocol information to the instruments from a Theranos Server and relays assay data to the Server for interpretation and distribution. Blood, plasma serum and control materials may be analyzed by the System. Calibration is performed at Theranos on a cartridge-lot-specific basis.

The System accepts a metered sample (15uL) from a proprietary sampling device or a pipette, dilutes it automatically to levels appropriate to each assay then executes an automated ELISA assay protocol. The protocol is selected from a set of released protocols available on the Theranos Server and identified by reading a bar code on each cartridge. The bar code is also linked to an assay lot-specific calibration algorithm. Assays are complete in about one hour.

Assays are typically grouped (multiplexed) in particular cartridges designed to monitor specific disease and therapeutic processes. For example, a cartridge designed to monitor acute and inflammatory processes measures IL-6, TNF-α and CRP. Customer is interested in use of the Theranos System and has sponsored a validation exercise at Theranos focused on the inflammatory marker cartridge.

In this exercise, many instruments (60) and three lots of cartridges were used for validation of system level performance: inter-intra device, cartridge, and assay performance.

2. Storage and Use

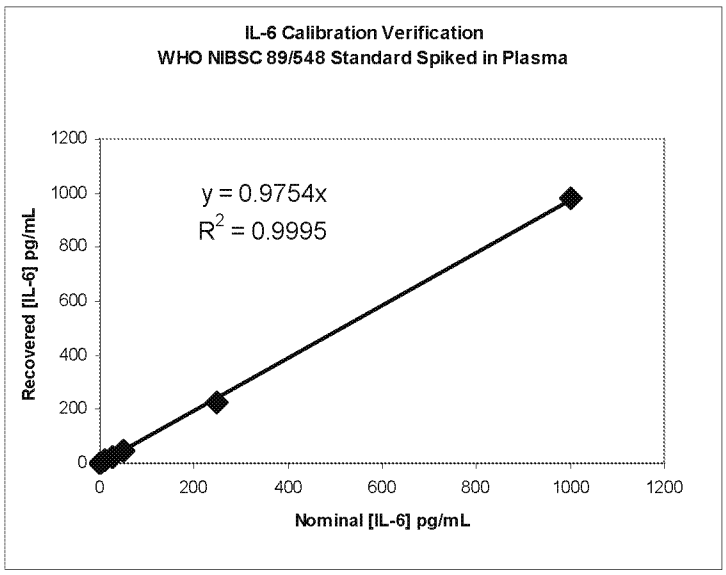
Theranos cartridges should be stored in the original unopened packaging in an upright position at 4°C. Theranos instruments require no user maintenance or calibration. User prompts are provided on a screen which is part of the instrument.

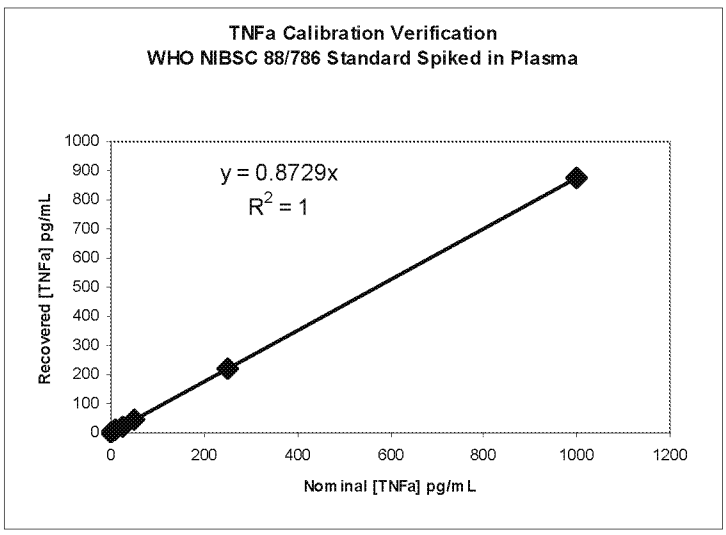
3. Calibration

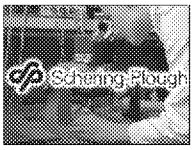
IL-6 and TNF-α assay calibration utilize recombinant analytes expressed in human-cell lines as calibration materials. These are reportedly more stable than recombinant analytes made in bacteria and more similar to the naturally occurring analytes. The CRP assay is calibrated with a human plasma-derived analyte. Theranos Systems assays recognize "natural", recombinant, and human-cell line expressed recombinant forms of IL-6 and TNF-α. Each lot of Theranos Cartridges is individually calibrated, the calibration equation is linked to the cartridge barcode and results are automatically computed on the Theranos data server. For this validation study, three cartridge lots were produced and calibrated.

NIBSC WHO Verification of Calibration

Exemplary assay responses are shown in Appendix A. Calibrations for IL-6, TNF-α and CRP were verified by testing the recovery of the current National Institute for Biological Standards and Control (NIBSC) World Health Organization (WHO) Reference Standards. The current WHO standard for IL-6 is NIBSC code 89/548 (recombinant protein produced in CHO cells with post translational modifications), for TNF-α NIBSC code 88/786 (a natural human protein derived from human BALL-1 cells), and for CRP NIBSC code 85/506 from human plasma. Spike recovery of all three WHO standards were within acceptable limits across the assay ranges as shown in the figures and tables below. Note that for the TNF- α assay we found low recovery (about 30%) of the WHO standard in a reference kit (R&D Systems Quantikine HS catalogue # HSTA00D, data shown in Appendix B). Therefore comparisons of sensitivity and slopes of assay correlations of results of the Theranos System with those of R&D Systems kits will show different results due to their respective calibrations. For example, the R&D Systems Assay would report a TNF-α value of 4 pg/mL when the Theranos Assay reports 12 pg/mL. If desired by a customer the Theranos System can be configured (in calibration algorithms) to provide results matching those of R&D Systems assays (or those of other predicate assay). It is our intention however to continue to perform primary calibration of Theranos assays using International Standard materials whenever possible since predicate assays not so calibrated may be subject to lot-to-lot variation in calibration.


IL-6 Calibration Verification
WHO NIBSC 89/548 Standard Spiked in Plasma
y = 0.9754x
R2 = 0.9995
Recovered [IL-6] pg/mL
Nominal [IL-6] pg/mL
0
200
400
600
800
1000
1200


TNFa Calibration Verification
WHO NIBSC 88/786 Standard Spiked in Plasma
y = 0.8729x
R2 = 1
Recovered [TNFa] pg/mL
Nominal [TNFa] pg/mL
0
100
200
300
400
500
600
700
800
900
1000
1200



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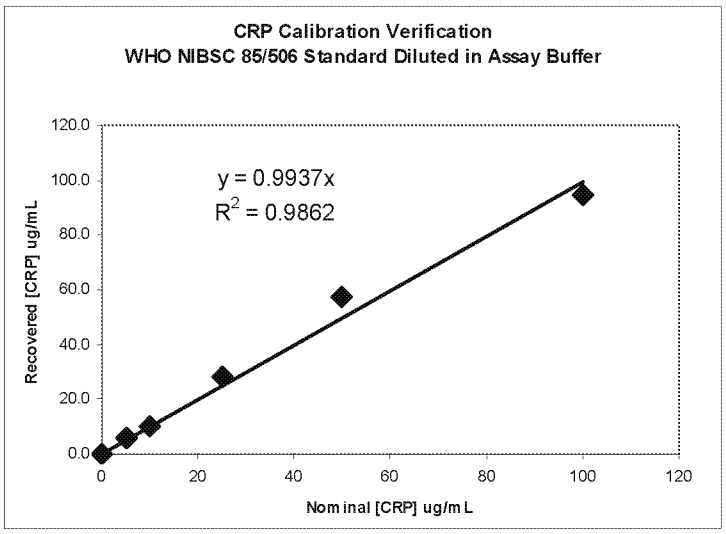
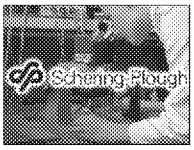


Theranos Systems Recovery of IL-6 (NIBSC code 89/548) Spiked in Plasma n=3 cartridges, 3 instruments per level					
[IL-6] IU/mL	**[IL-6] pg/ml**	**Recovered [IL-6] pg/mL**	**CV %**	**Minus Endogenous**	**% Recovery**
100	1000	981.1	11	980.1	98
25	250	227.1	16	226.2	90
5	50	45.2	10	44.2	88
3	25	21.5	8	20.5	82
1	10	10.5	9	9.5	95
0	0	1.0	47	0.0	N/A

Theranos Systems Recovery of TNF-α (NIBSC code 88/786) Spiked in Plasma n=3 cartridges, 3 instruments per level					
[TNFa] IU/mL	**[TNFa] pg/mL**	**Recovered [TNF-α] pg/mL**	**CV %**	**Minus Endogenous**	**% Recovery**
46.5	1000	873.4	3	873.0	89
11.6	250	218.7	3	218.3	96
2.3	50	44.0	10	43.5	96
1.2	25	20.9	22	20.4	95
0.5	10	10.9	19	10.5	100
0	0	0.4	14	0.0	N/A

Theranos Systems Recovery of CRP (NIBSC code 85/506) in Assay Buffer n=3 cartridges, 3 instruments per level				
[CRP] IU/mL	**[CRP] ug/ml**	**Recovered [CRP] ug/mL**	**CV %**	**% Recovery**
98	100	94.6	2	95
49	50	57.4	18	115
24.5	25	28.1	15	113
10	10	10.2	14	102



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4.9	5	5.7	20	114
0	0	0.0	30	N/A

4. Range

Reportable ranges based on calibration to WHO standards determined for these assays are:

Assay	Low	High
IL-6	2 pg/mL	1000 pg/mL
TNF-α	4[1] pg/mL	1000 pg/mL
CRP	0.05 ug/mL	100 ug/mL

As shown below, all three tested lots support these ranges[2].

5. Quantitation Limits

Assay calibrations and determination of Lower Limit of Quantitation (LLOQ) and Upper Limit of Quantitation (ULOQ) were performed and analyzed by proprietary software. Assay responses were fitted by a four-parameter equation and LLOQ and ULOQ determined according to FDA criteria. Calibrators were run in triplicate on three days (consecutive or non-consecutive) on 36 instruments for a total of nine cartridges per level, at 12 levels.

Summary of Calibration Analysis for three Cartridge Lots

Lot 2455142005	**IL-6**	**TNF-α**	**CRP**
LLOQ	1.3 pg/mL	6.3 pg/mL	0.05 ug/mL
ULOQ	1000 pg/mL	1000 pg/mL	150 ug/mL
Lot 2455146006	**IL-6**	**TNF-α**	**CRP**
LLOQ	1.3 pg/mL	6.3 pg/mL	0.05 ug/mL
ULOQ	1000 pg/mL	1000 pg/mL	150 ug/mL
Lot 2455156002	**IL-6**	**TNF-α**	**CRP**
LLOQ	2.3 pg/mL	6.3 pg/mL	0.05 ug/mL
ULOQ	1000 pg/mL	1000 pg/mL	150 ug/mL

Limits of detection (LOD)

The range in the Limits of detection calculated as 2*Signal SD/Slope of dose response (□signal/□conc) are reported for the three lots of Theranos cartridges. Comparison data are also given for R&D Systems assays Minimum Detectable Dose "MDD" (which is equivalent to LOD). In addition to the calibration issue for the R&D Systems TNF-α assay discussed above

[1] Equivalent to 1 pg/mL in the R&D Systems assay calibrated using R&D Systems calibrators

[2] The lower limit of the reportable range of the TNF-α assay has been extended below the LLOQ so as not to restrict the reportable range too much. The LLOQ is higher than anticipated due to unexpectedly high imprecision of the assay in the cartridge lots used for validation compared with other cartridge lots used in pre-clinical work. We are presently investigating the root cause of this imprecision.

which gives a four-fold lower limit for R&D Systems, we believe the calculation of MDD performed by R&D Systems may be compromised (falsely low) by the inability of any known spectrometer to report optical density to the required precision needed to support the calculated values.

The CRP MDD reported by R&D Systems is highly misleading since it represents the concentration in the assay rather than in the sample (which "must be diluted" according to their package insert prior to assay). Note that the Theranos assay uses a sample which is diluted 5000-fold. If we compare the actual sensitivity *in the assay medium* the Theranos value would be about 0.006 ng/mL.

Assay System	IL-6 (pg/mL)	TNF-α(pg/mL)	CRP (ng/mL)
Theranos	0.9 – 1.5	3.7 – 5.2	28 - 31
R&D Systems	0.02 – 0.11	0.04 – 0.19	0.005 – 0.22
R&D Systems[3]		0.16 – 0.76	

6. Precision and Accuracy

Plasma with low endogenous analyte levels was spiked with three levels of the analytes were measured in 16 cartridges per level on 48 instruments. Recovery of the spiked analyte was good. Imprecision (% CV) ranged from 10 - 25 %. Note that the imprecision cited includes both instrument-instrument and cartridge-cartridge variance.

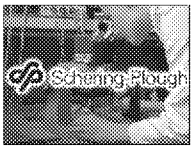
Spiked Plasma Samples (n=16 cartridges, n=48 instruments)

Nominal [IL-6] pg/mL	**Recovered [IL-6] pg/mL**	**StDev**	**CV %**	**% Recovery**
800.3	806.9	79.8	9.9	101
50.3	50.5	4.7	9.2	100
5.3	5.1	0.8	15.5	96
Nominal [TNFa] pg/mL	**Recovered [TNFa] pg/mL**	**StDev**	**CV %**	**% Recovery**
500.3	418.9	39.6	9.5	84
50.3	42.7	5.1	12.0	85
12.3	12.9	3.2	24.6	105
Nominal [CRP] ug/mL	**Recovered [CRP] ug/mL**	**StDev**	**CV %**	**% Recovery**
50.1	50.4	10.0	19.9	101
1.6	1.6	0.3	16.8	97
0.1	0.1	0.0	20.6	103

7. Specificity

Assays were tested for cross reactivity and interference by the factors listed below, at high, mid and low analyte levels. Potential cross-reactants were selected based on package inserts of recognized predicate methods and added at levels deemed to be higher than those likely to be

[3] Recalculated to reflect calibration to WHO standard material



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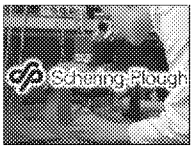
found in clinical samples. No significant cross reactivity or interference was observed for any of the assays by any of the tested factors at all analyte levels tested.

IL-6 Assay Specificity Test in Spiked Plasma (n=3 cartridges, 3 instruments per level)					
Substance	**[Test Substance] ng/mL**	**Target [IL-6] pg/mL**	**Recovered [IL-6] pg/mL**	**CV %**	**% Recovery**
Control	0	1000.3	1100.3	7.8	110
	0	90.3	95.8	16.6	106
	0	8.3	9.4	4.8	113
IL-1α	10	1000.3	939.2	2.9	94
	10	90.3	97.0	15.7	107
	10	8.3	9.0	6.9	108
IL-2	10	1000.3	1047.7	1.7	105
	10	90.3	86.7	9.4	96
	10	8.3	8.7	22.3	105
IL-3	10	1000.3	950.0	12.7	95
	10	90.3	91.9	4.6	102
	10	8.3	7.9	4.4	95
IL-4	10	1000.3	908.0	10.9	91
	10	90.3	79.9	16.7	88
	10	8.3	8.1	18.1	97
IL-6 sR	50	1000.3	914.9	18.0	91
	50	90.3	81.2	1.3	90
	50	8.3	8.0	29.0	96
IL-7	10	1000.3	895.0	10.0	89
	10	90.3	78.1	9.1	87
	10	8.3	8.2	9.4	99
IL-8	10	1000.3	927.8	9.7	93
	10	90.3	82.3	17.1	91
	10	8.3	8.4	17.6	101
IL-11	10	1000.3	897.5	12.5	90
	10	90.3	90.3	6.1	100
	10	8.3	7.9	2.2	95
IL-12	10	1000.3	837.6	8.4	84
	10	90.3	85.8	14.7	95
	10	8.3	6.8	18.1	82
CNTF	10	1000.3	900.6	8.4	90
	10	90.3	95.3	5.8	106
	10	8.3	8.9	22.4	107
G-CSF	10	1000.3	925.0	18.7	92
	10	90.3	90.2	12.8	100
	10	8.3	9.7	6.9	117
sgp130	1000	1000.3	895.5	17.0	90
	1000	90.3	88.6	2.0	98



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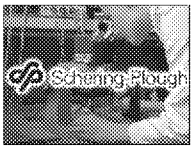
IL-6 Assay Specificity Test in Spiked Plasma (n=3 cartridges, 3 instruments per level)					
Substance	**[Test Substance] ng/mL**	**Target [IL-6] pg/mL**	**Recovered [IL-6] pg/mL**	**CV %**	**% Recovery**
	1000	8.3	9.4	3.2	114
LIF R	50	1000.3	895.2	2.8	89
	50	90.3	78.5	16.5	87
	50	8.3	8.9	19.8	107
OSM	10	1000.3	945.4	9.5	95
	10	90.3	77.1	10.0	85
	10	8.3	6.9	16.8	83
TNF-β	10	1000.3	919.6	8.6	92
	10	90.3	83.3	15.8	92
	10	8.3	9.4	7.8	113
IL-1β	10	1000.3	901.2	8.1	90
	10	90.3	85.7	17.6	95
	10	8.3	7.5	10.5	90
sTNF RI	10	1000.3	1025.2	9.2	102
	10	90.3	83.4	11.4	92
	10	8.3	9.4	16.5	114
sTNF RII	10	1000.3	963.3	13.8	96
	10	90.3	90.7	10.2	100
	10	8.3	9.3	21.0	112

TNF-α Assay Specificity Test in Spiked Plasma (n=3 cartridges, 3 instruments per level)					
Substance	**[Test Substance] ng/mL**	**Target [TNFa] pg/mL**	**Recovered [TNFa] pg/mL**	**CV %**	**% Recovery**
Control	0	900.3	883.7	4.1	98
	0	90.3	85.4	4.1	95
	0	8.3	8.3	40.4	100
IL-1α	10	900.3	849.1	5.5	94
	10	90.3	89.6	12.7	99
	10	8.3	8.8	16.0	106
IL-2	10	900.3	855.2	23.5	95
	10	90.3	90.8	7.9	101
	10	8.3	9.6	18.5	116
IL-3	10	900.3	836.5	23.5	93
	10	90.3	74.3	5.4	82
	10	8.3	8.2	29.2	98
IL-4	10	900.3	884.6	6.9	98
	10	90.3	89.5	8.5	99
	10	8.3	7.0	49.3	84
IL-6 sR	50	900.3	874.0	23.5	97
	50	90.3	77.8	13.8	86
	50	8.3	8.6	34.8	103
IL-7	10	900.3	871.9	6.3	97
	10	90.3	82.8	37.1	92



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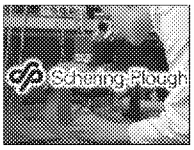
TNF-α Assay Specificity Test in Spiked Plasma (n=3 cartridges, 3 instruments per level)					
Substance	**[Test Substance] ng/mL**	**Target [TNFa] pg/mL**	**Recovered [TNFa] pg/mL**	**CV %**	**% Recovery**
	10	8.3	7.6	22.9	91
IL-8	10	900.3	774.4	1.8	86
	10	90.3	83.4	13.5	92
	10	8.3	7.9	12.6	95
IL-11	10	900.3	901.8	1.5	100
	10	90.3	90.7	19.6	100
	10	8.3	9.3	36.8	112
IL-12	10	900.3	770.9	7.3	86
	10	90.3	77.4	15.8	86
	10	8.3	7.9	56.7	96
CNTF	10	900.3	920.1	6.0	102
	10	90.3	82.5	9.7	91
	10	8.3	8.7	18.9	105
G-CSF	10	900.3	1052.6	3.7	117
	10	90.3	95.6	20.7	106
	10	8.3	9.1	9.6	110
sgp130	1000	900.3	891.3	16.8	99
	1000	90.3	93.8	9.1	104
	1000	8.3	10.1	25.1	122
LIF R	50	900.3	781.5	20.7	87
	50	90.3	87.3	15.2	97
	50	8.3	9.1	12.1	110
OSM	10	900.3	862.1	10.6	96
	10	90.3	85.2	23.8	94
	10	8.3	7.4	54.1	89
TNF-β	10	900.3	804.0	24.7	89
	10	90.3	90.7	16.4	100
	10	8.3	7.7	32.3	92
IL-1β	10	900.3	900.0	17.3	100
	10	90.3	83.1	16.6	92
	10	8.3	8.3	33.1	101
sTNF RI	10	900.3	833.0	21.8	93
	10	90.3	86.4	19.5	96
	10	8.3	6.7	21.6	80
sTNF RII	10	900.3	801.3	8.9	89
	10	90.3	93.6	3.0	104
	10	8.3	8.2	14.2	99

CRP Assay Specificity Test in Assay Buffer (n=3 cartridges, 3 instruments per level)					
Substance	**[Test Substance] ng/mL**	**Target [CRP] ug/ml**	**Recovered [CRP] ug/ml**	**CV %**	**% Recovery**



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Control	0	50	53.0	16	106
	0	10	8.1	34	81
	0	0.75	0.7	13	91
Pentraxin-2/SAP	30	50	49.2	19	98
	30	10	8.9	9	89
	30	0.75	0.8	4	102
Pentraxin-3/TSG-14	10	50	40.6	7	81
	10	10	8.2	14	82
	10	0.75	0.7	5	100

8. Linearity

A plasma sample with low endogenous analyte levels was spiked with known levels of IL-6, TNF-α, and CRP then diluted serially with the unspiked plasma. All assays showed an appropriate linear dilution response across the dilution range (500 – 2000-fold). Data are tabulated and graphed below.

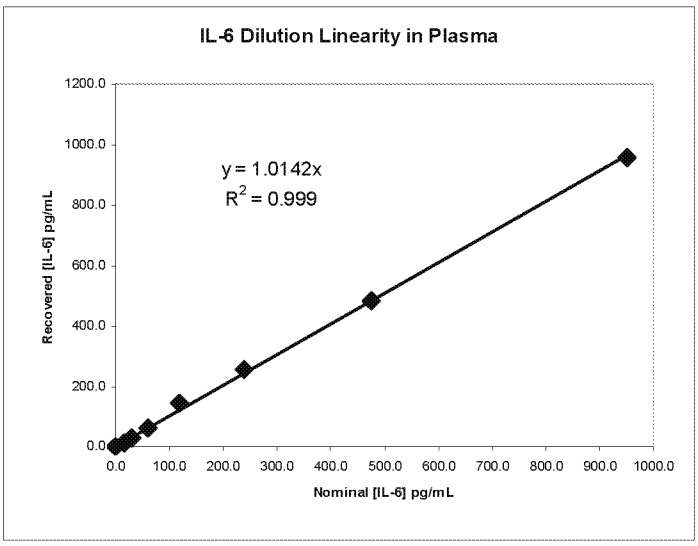
Dilution Linearity in Plasma, Multiplexed Assays (n=3 cartridges, 3 instruments per level)

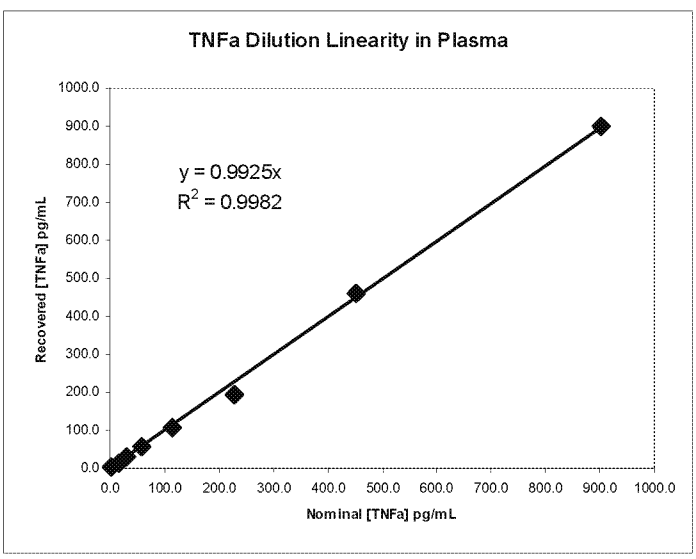
IL-6				
Spiked [IL-6] pg/mL	**[Expected] pg/ml**	**[Recovered] pg/mL**	**CV %**	**% Recovery**
950	950.5	958.1	7	101
	475.5	480.9	11	101
	238.0	256.1	18	108
	119.2	143.9	25	121
	59.8	62.3	3	104
	30.1	28.3	23	94
	15.3	13.3	34	87
	0.5	0.5	88	100

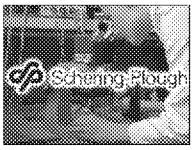
TNF-α				
Spiked [TNFa] pg/mL	**[Expected] pg/ml**	**[Recovered] pg/mL**	**CV %**	**% Recovery**
900	902.7	899.2	11	100
	452.7	461.5	9	102
	227.7	194.6	6	85
	115.2	105.0	11	91
	59.0	56.1	2	95
	30.9	30.6	4	99
	16.8	14.9	26	89
	2.7	2.7	14	100

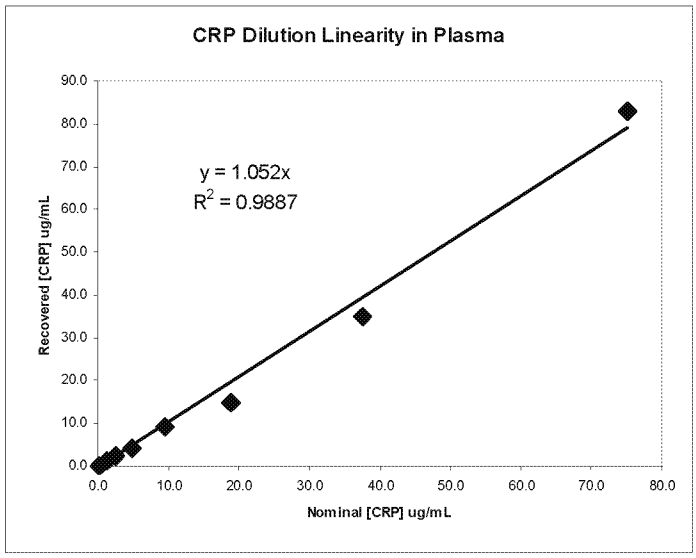
CRP				
Spiked [CRP] ug/mL	**[Expected] ug/ml**	**[Recovered] ug/mL**	**CV %**	**% Recovery**
75	75.1	82.8	34	110
	37.6	35.0	0	93
	18.8	14.7	10	78
	9.5	9.1	12	96

	4.8	4.1	8	85
	2.4	2.4	7	98
	1.3	1.3	15	102
	0.1	0.1	29	100







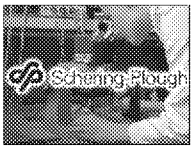


9. Matrix Effects

Plasma or serum containing various potentially interfering factors or substances were spiked with known levels of analyte and the resulting recovery of the spiked analyte calculated after correction for endogenous analyte. None of the assays showed interference from icteric, hemolyzed, lipemic, or rheumatoid factor-positive samples as shown in the tables below

NORMAL SERUM Sample: PromedDx 10739123 (n=3 cartridges, 3 instruments per level)

Spiked [IL-6] pg/mL	Recovered [IL-6] pg/mL	CV %	Minus Endogenous	% Recovery
1000	1019.1	14	1015.82	102
250	224.9	4	221.58	89
50	47.7	14	44.42	89
25	25.3	6	22.01	88
10	12.6	9	9.29	93
0	3.3	43	0.00	
Spiked [TNFa] pg/mL	**Recovered [TNFa] pg/mL**	**CV %**	**Minus Endogenous**	**% Recovery**
1000	1019.1	14	1014.7	101
250	224.9	4	220.5	88
50	47.7	14	43.3	87
25	25.3	6	20.9	84
10	12.6	9	8.2	82
0	4.4	60	0.0	
Spiked [CRP] ug/mL	**Recovered [CRP] ug/mL**	**CV %**	**Minus Endogenous**	**% Recovery**
100	107.4	11	107.3	107
50	49.3	13	49.3	99
25	25.0	23	24.9	100
10	9.6	41	9.5	95
5	5.9	17	5.8	116



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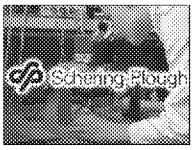
0	0.1	12	0.0	



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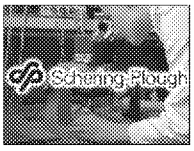
LIPEMIC SERUM Sample: Vital Products SFB8315 (n=3 cartridges, 3 instruments per level)

Spiked [IL-6] pg/mL	Recovered [IL-6] pg/mL	CV %	Minus Endogenous	% Recovery
1000	872.5	15	868.8	87
250	214.1	4	210.4	84
50	47.8	15	44.1	88
25	24.5	6	20.8	83
10	14.4	19	10.7	107
0	3.7	12	0.0	
Spiked [TNFa] pg/mL	**Recovered [TNFa] pg/mL**	**CV %**	**Minus Endogenous**	**% Recovery**
1000	965.0	17	962.8	96
250	230.8	15	228.6	91
50	56.6	40	54.4	109
25	25.4	13	23.2	93
10	14.8	14	12.6	126
0	2.2	32	0.0	
Spiked [CRP] ug/mL	**Recovered [CRP] ug/mL**	**CV %**	**Minus Endogenous**	**% Recovery**
100	119.4	36	119.1	119
50	54.2	40	53.9	108
25	24.4	25	24.1	96
10	10.4	9	10.1	101
5	5.8	15	5.6	111
0	0.2	12	0.0	

HEMOLYZED PLASMA Sample: Stanford W070509118560 (n=3 cartridges, 3 instruments per level)

Spiked [IL-6] pg/mL	Recovered [IL-6] pg/mL	CV %	Minus Endogenous	% Recovery
1000	1010.9	10	1010.0	101
250	274.6	13	273.7	109
50	51.6	2	50.7	101
25	26.8	11	25.9	104
10	10.5	12	9.6	96
0	0.9	41	0.0	
Spiked [TNFa] pg/mL	**Recovered [TNFa] pg/mL**	**CV %**	**Minus Endogenous**	**% Recovery**
1000	898.7	14	895.1	90
250	223.5	12	219.9	88
50	44.2	11	40.6	81
25	27.7	23	24.1	96
10	12.0	23	8.4	84
0	3.6	14	0.0	
Spiked [CRP] ug/mL	**Recovered [CRP] ug/mL**	**CV %**	**Minus Endogenous**	**% Recovery**
100	119.6	10	119.5	119
50	54.0	10	53.9	108
25	22.5	14	22.4	90
10	11.6	3	11.5	115
5	5.6	11	5.5	110
0	0.1	4	0.0	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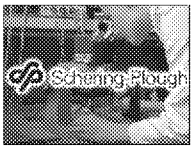

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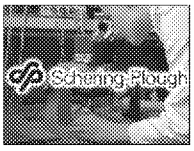
ICTERIC SERUM Sample: PromedDx 10739123 (n=3 cartridges, 3 instruments per level)

Spiked [IL-6] pg/mL	Recovered [IL-6] pg/mL	CV %	Minus Endogenous	% Recovery
1000	986.0	9	983.4	98
250	282.4	12	279.7	112
50	55.8	10	53.2	106
25	28.1	7	25.4	102
10	11.8	16	9.2	92
0	2.6	53	0.0	
Spiked [TNFa] pg/mL	**Recovered [TNFa] pg/mL**	**CV %**	**Minus Endogenous**	**% Recovery**
1000	969.8	5	967.4	97
250	219.6	22	217.2	87
50	45.0	11	42.6	85
25	24.5	5	22.1	88
10	10.6	22	8.2	82
0	2.4	17	0.0	
Spiked [CRP] ug/mL	**Recovered [CRP] ug/mL**	**CV %**	**Minus Endogenous**	**% Recovery**
100	109.5	8	108.4	108
50	41.7	80	40.6	81
25	29.6	14	28.4	114
10	10.1	11	9.0	90
5	6.4	19	5.3	106
0	1.1	3	0.0	

RHEUMATOID FACTOR POSITIVE SERUM Sample: Vital Products SFB7884 (n=3 cartridges, 3 instruments per level)

Spiked [IL-6] pg/mL	Recovered [IL-6] pg/mL	CV %	Minus Endogenous	% Recovery
1000	1118.0	10	1097.9	110
250	286.9	9	266.7	107
50	77.7	13	57.6	115
25	46.3	12	26.2	105
10	30.4	6	10.2	102
0	20.1	6	0.0	
Spiked [TNFa] pg/mL	**Recovered [TNFa] pg/mL**	**CV %**	**Minus Endogenous**	**% Recovery**
1000	1116.4	11	1112.3	111
250	228.9	5	224.8	90
50	48.0	13	43.9	88
25	24.2	13	20.1	80
10	14.0	20	9.9	99
0	4.1	27	0.0	
Spiked [CRP] ug/mL	**Recovered [CRP] ug/mL**	**CV %**	**Minus Endogenous**	**% Recovery**
100	110.9	18	105.8	106
50	49.1	17	44.0	88
25	34.2	29	29.0	116
10	15.5	9	10.3	103
5	10.9	11	5.7	114



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0	5.2	28	0.0	

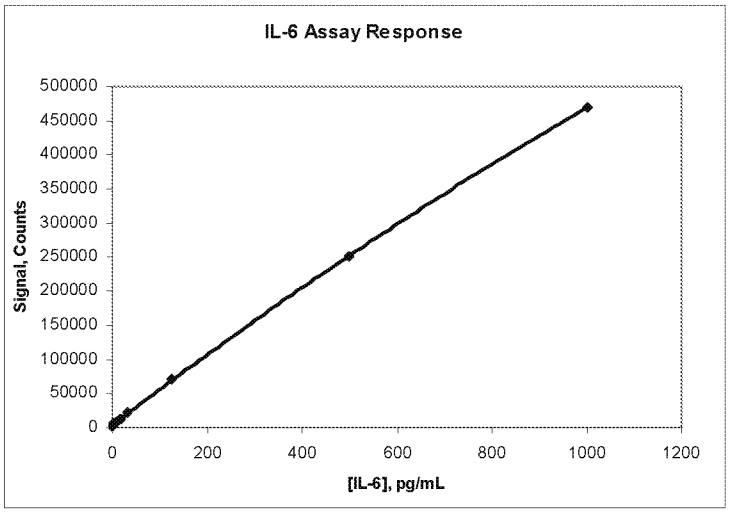
10. Stability

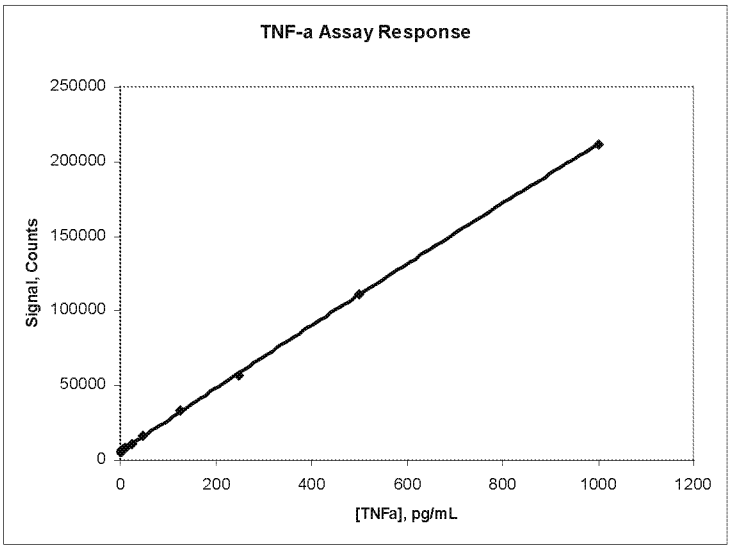
The stability of component reagents for the present assays has been studied individually in lots made previous to the present study. The capture surfaces were stable for over 12 months, and the detection conjugates for at least six months. Stability of the integrated cartridges used for this validation report stored at 4C is being monitored and an updated report will include this data. Cartridges are initially assigned an expiry date of three months post manufacture.

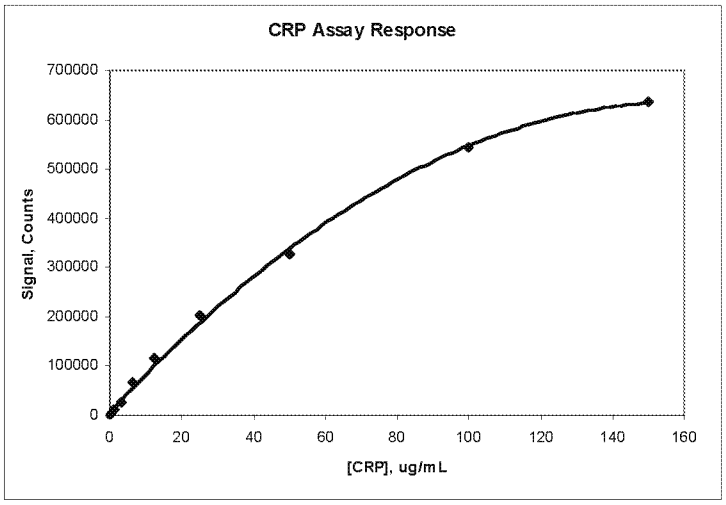
Conclusions:

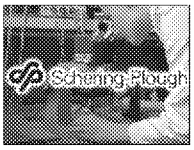
The Theranos IL-6, TNF-α, CRP assay multiplex has been shown to give more accurate and precise results for three independently calibrated cartridge lots and all the many instruments used than current "gold standard" reference methods. Assay calibration has been established using WHO or other standard materials. Lower and upper levels of quantitation have been established. The assays are specific for their respective analytes when tested against potential cross reactants and are not interfered with by agents that may cause problems in immunoassays. Dilution linearity is satisfactory for all the assays. Assay cartridge stability studies are underway.

Appendix A


IL-6 Assay Response
Signal, Counts
500000
450000
400000
350000
300000
250000
200000
150000
100000
50000
0
0
200
400
600
800
1000
1200
[IL-6], pg/mL


TNF-a Assay Response
Signal, Counts
250000
200000
150000
100000
50000
0
0
200
400
600
800
1000
1200
[TNFa], pg/mL


CRP Assay Response
Signal, Counts
700000
600000
500000
400000
300000
200000
100000
0
0
20
40
60
80
100
120
140
160
[CRP], ug/mL



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Appendix B

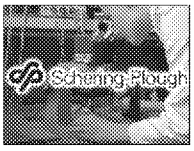
Comparison of Theranos Systems TNFa Calibration to Other Available Commercial Methods

Plasma samples were spiked with WHO TNF-a Standard (NIBSC code 88/786) and run in Theranos Systems and in R&D Quantikine High Sensitivity Human TNF-α ELISA (catalogue # HSTA00D). The results are shown below.

THERANOS SYSTEMS Recovery of TNFa WHO Standard Spiked in Plasma

Nominal Spike		1pg/mL = 0.0465 IU/mL			
[TNFa] IU/ml	**[TNFa] pg/ml**	**Calc. pg/mL**	**Minus Endogenous**	**Calc. IU/mL**	**% Recovery**
0	0	5.2	0.0		
0.1	2.5	8.1	2.9	0.1	118
0.2	5	11.5	6.3	0.3	126
0.5	10	14.9	9.7	0.5	97
1.2	25	35.9	30.8	1.4	123
2.3	50	57.6	52.4	2.4	105
11.6	250	217.6	212.5	9.9	85
46.5	1000	1120.6	1115.4	51.9	112

R&D QUANTIKINE HS ELISA Recovery of TNFa WHO Standard Spiked in Plasma					
Nominal Spike		1pg/mL = 0.0465 IU/mL			
[TNFa] IU/ml	**[TNFa] pg/ml**	**Calc. pg/mL**	**Minus Endogenous**	**Calc. IU/mL**	**% Recovery**
0	0	0.2	0.0		
0.1	2.5	1.0	0.8	0.04	32
0.2	5	1.8	1.6	0.07	32
0.5	10	3.2	3.0	0.14	30
1.2	25	7.3	7.1	0.3	28
2.3	50	15.0	14.8	0.7	30
11.6	250	83.6	83.4	3.9	33
46.5	1000	308.0	307.7	14.3	31



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