From: Surekha Gangakhedkar <surekhag@theranos.com>
Sent: Wednesday, June 9, 2010 12:20 PM
To: Victoria Sung <VSung@celgene.com>; Brian Lindberg <blindberg@theranos.com>; Lisa Serme <lserme@celgene.com>; Hem Singh <hsingh@celgene.com>; Nandita Sriram <nsriram@theranos.com>
Cc: Sharianne Louie <slouie@celgene.com>; William Smith <wsmith@celgene.com>
Subject: RE: ACE-011 REN-001 Timelines
Attach: Progesterone Assay Development Report - External_06-08-2010.doc

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Hi Vicki,

Attached is the Progesterone report. I will be sending you the others shortly. Thanks for your patience.

-Surekha

Surekha Gangakhedkar
Team Manager, Assay System
Theranos Inc.
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==========

From: Victoria Sung [mailto:VSung@celgene.com]
Sent: Wednesday, June 09, 2010 12:17 PM
To: Brian Lindberg; Surekha Gangakhedkar; Lisa Serme; Hem Singh; Nandita Sriram
Cc: Sharianne Louie; William Smith
Subject: RE: ACE-011 REN-001 Timelines

One more request; for the PD assays that we are including in Part 1, we have not yet seen any assay development documentation / validation reports. Surekha, when we last met, you mentioned that you could send these to us. At this time, I would ask that we are permitted to have a look at the development reports for LH, FSH, Progesterone and Estradiol BEFORE we implement in the field. It seems reasonable that we gain some familiarity with assay details prior to using them in our clinical trial.

Thank you and regards,
Vicki

From: Brian Lindberg [mailto:blindberg@theranos.com]
Sent: Wednesday, June 09, 2010 9:54 AM
To: Victoria Sung; Surekha Gangakhedkar; Lisa Serme; Hem Singh; Nandita Sriram
Cc: Sharianne Louie; William Smith
Subject: RE: ACE-011 REN-001 Timelines

Ok that makes sense. I completely agree we need to keep things as simple as possible for the staff at the clinical sites. We expect to have more than two assays per cartridge for Part 2.

From: Victoria Sung [mailto:VSung@celgene.com]
Sent: Wednesday, June 09, 2010 9:48 AM
To: Brian Lindberg; Surekha Gangakhedkar; Lisa Serme; Hem Singh; Nandita Sriram
Cc: Sharianne Louie; William Smith
Subject: RE: ACE-011 REN-001 Timelines

Hi Brian,
We had discussed the issue of readers with Surekha, Gary and Elizabeth the last time we met with them and there is a very good reason for the multiple readers at each site. The clinical site staff will be very busy with multiple patients and likely will be unable to put a cartridge into a machine, wait around for the read, remove it and put another cartridge in, etc.. Therefore, we have conveyed to the sites that we will have multiple readers so that the staff will need only to pipet sample only once to a number of cartridges, pop them into the readers and walk away. Having said this, we figured that there would be multiple machines at each site for part 2…however, our hope was that we could assay for more than two analytes per cartridge. Our goal is to make life for the clinical staff as simple (and least time-consuming) as possible…this will optimize the sampling/data collection process and encourage site staff to participate in future studies.

It's too bad about the Hgb assay; I think we prefer not to be adding cartridges to the process in the middle of part 1; however, if it is simply a test surface added to an existing cartridge (like the PK cartridge), that should be OK. Lisa and Nalini can probably better answer your question about enrolling patients at each site.
Thanks,
Vicki

From: Brian Lindberg [mailto:blindberg@theranos.com]
Sent: Wednesday, June 09, 2010 9:35 AM
To: Victoria Sung; Surekha Gangakhedkar; Lisa Serme; Hem Singh; Nandita Sriram
Cc: Sharianne Louie; William Smith
Subject: RE: ACE-011 REN-001 Timelines

If 66 cartridges per site are too many we don't need to send them all at once. I am still trying to get a feel for the logistics of the study and I felt it would be safest to have two full sets of cartridges at each site. Do we anticipate enrolling as many as 2 patients at any one site immediately? If this is not the case we can send half that number in preparation for the first patient at each site and then send more cartridges at a later date.

The Hgb assay is not ready at this time. As soon as it is ready we can add it into the PK cartridge and have it out to you. I don't have a definitive date for when it will be ready though. With the PD assays, we felt that we could provide the most accurate results at this time by splitting the assays into two cartridges. I don't know how many different cartridges will be supplied for Part 2, but I wouldn't be concerned at this time about finding space for too many readers. If space becomes an issue I don't see a problem with staggering tests to make better use of fewer readers. For instance in Part 1, we could potentially ship just one reader and run the three cartridges one after the other on the one reader. We felt adding this degree of complication to running the cartridges was unnecessary though.

Let me know what you are thinking on all this and we can work to alter our shipping plans to better fit your needs.

Thanks!
Brian

From: Victoria Sung [mailto:VSung@celgene.com]
Sent: Tuesday, June 08, 2010 4:21 PM
To: Brian Lindberg; Surekha Gangakhedkar; Lisa Serme; Hem Singh; Nandita Sriram
Cc: Sharianne Louie; William Smith
Subject: RE: ACE-011 REN-001 Timelines

Brian-
Thank you! This is very useful information and exactly what we have been hoping to find out from you and Surekha. A

few questions:

1) When the Translational Development team met with Theranos scientists last month, we were left with the impression that the Hgb assay, one of our highest priority assays, would be ready for Part 1 and might be included on the same cartridge as the PK assay…is this no longer the case?
2) Are the LH, FSH, Progesterone and Estradiol assays are on two separate cartridges because there will be extra assay controls on each cartridge? With 6 (or 8?) test surfaces, I would've thought that we could fit more assays per cartridge.

Nalini and Lisa: if there are going to be four readers per site for 4 PD assays, imagine how many there will be when we have all 15+ PD assays up and running for Part 2! Depending on bench space at the clinical sites, we may need to get racks for the readers and we also should definitely get fridges in which to store the 66 cartridges (will they all fit into one under bench fridge?).
Vicki

From: Brian Lindberg [mailto:blindberg@theranos.com]
Sent: Tuesday, June 08, 2010 4:07 PM
To: Victoria Sung; Surekha Gangakhedkar; Lisa Serme; Hem Singh; Nandita Sriram
Cc: Sharianne Louie
Subject: RE: ACE-011 REN-001 Timelines

Alright so we will be shipping 3 different cartridges to the clinical sites:

PK with ACE-011 assay
PD with LH and FSH assays
PD with Progesterone and Estradiol assays

I am still working out how many devices we will be supplying to each site. I anticipate sending 3 but may send a 4th as well to serve as a backup in the unlikely event that one malfunctions. For cartridges, I plan on initially shipping 34 of PK ACE-011, 16 PD FSH/LH, and 16 PD Prog/Estrad to each site. This should be enough to take care of each time point for two patients per site (17 timepoints for PK and 8 timepoints for both PD cartridges). I hope that information is useful. Continue to let me know if you have any questions or concerns.

Warmest regards,
Brian

From: Victoria Sung [mailto:VSung@celgene.com]
Sent: Tuesday, June 08, 2010 9:32 AM
To: Surekha Gangakhedkar; Lisa Serme; Hem Singh; Brian Lindberg; Nandita Sriram
Cc: Sharianne Louie
Subject: ACE-011 REN-001 Timelines

Hello,
Just to follow up on my e-mail below, we had a project team meeting this morning at which it was decided that cartridges and readers should probably be deployed to clinical sites by June 25. This date was determined by the fact that all sites will likely be enrolled in July and that the clinical site personnel need to be trained to use the Theranos readers prior to this time. Our hope is that following the June 18 training, the readers, cartridges and user manuals can be shipped to the various clinical sites and that training can commence at the end of June/beginning of July.

I've copied Lisa Serme and Nalini Singh on this e-mail as they are the clinical operations manager and scientist for this trial and will be coordinating activities at the clinical sites. Please let Lisa and Nalini know how many and which assays will be included on the cartridge(s) so that they can let the sites know how many cartridges and readers are expected to ship to each site. Also, would you please describe the method of shipping for these materials?

We're getting very close to starting…it will be an exciting next few weeks and we look forward to working with Theranos to implement our plans!
Thanks for your help.
Best,
Vicki

From: Victoria Sung
Sent: Monday, June 07, 2010 1:22 PM
To: Surekha Gangakhedkar
Cc: Gary Frenzel; Elizabeth Holmes; Sharianne Louie
Subject: RE: ACE-011 REN-001

Hi Surekha,
I have been in contact with Brian and we have identified June 18 as a date for training to take place.

Since we're getting close to deploying the cartridges and readers, can we please review which assays are likely to be included in the cartridge for part 1? I think we talked about hemoglobin and a number of the hormones but probably not all of them…and for the few that are assayed in Part 1, we'd appreciate seeing whatever reports (complete or not) you have for assay development/validation prior to initiating use of the readers at the clinical sites. I'll keep you posted as to when patients enroll; I think it will be fairly quickly at each of four potential sites.

Thank you and best regards,
Vicki

From: Surekha Gangakhedkar [mailto:surekhag@theranos.com]
Sent: Friday, June 04, 2010 11:37 AM
To: Victoria Sung
Cc: Gary Frenzel; Elizabeth Holmes; Steve Ritland; Brian Lindberg; Nandita Sriram
Subject: RE: ACE-011 REN-001

Hi Victoria,

To clarify, our plan is to deploy devices and cartridges, both PK and some PD at the sites for Part 1. We have a dedicated client solutions team available for training, installation, and deployment immediately. I have copied our Client solutions team (Nandita & Brian) on this email for you to coordinate the training with them. Regarding the time points to test for the PD markers, we would like to test at all available time points.

Thanks,

Surekha

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Assay Development Report
June 08, 2010

Analyte Background 2
Antibody Screening Set Summary 5
Appendix A: Progesterone in Blood and Plasma 33
Assay accuracy Clinical Sample Assay correlation 29
Assay Development 2
Assay Information 2
Assay Optimization 5
Assay Reagents 3
Assay Specifications (Including LLOQ and ULOQ) 2
Buffer Effects: Testing Different Sample Diluents 13
Calibrator Comparison 20
Capture Stability 26
Capture Titration, Protocol Comparison, and Surface Optimization 9
Conclusions 32
Cross Reactivity and Interference 6
Detection Conjugate Titration 12
Dilution Linearity 22
Matrix Effects 27
Max Range 29
Notes on Troubleshooting Done to Develop a Small Molecule Assay for a Steroid Hormone 14
Precision and CV Test 15
Protocols 4
Reagent Handling and Storage (Analyte) 4
Recovery in Whole Blood and Plasma and Hematocrit Effect 23
Reference Assays 2
ULOQ and LLOQ 26
Whole Blood and Plasma Screen 8

Assay Development Report
Progesterone

A) Assay Development

I) Assay Information

1. Analyte Background

Progesterone is an important steroid hormone that functions primarily in the regulation of menstruation and pregnancy in females, although the hormone is also produced in males. In females, it is largely secreted by the corpus luteum and placenta. In the body cholesterol is converted into pregnenolone, which is then made into progesterone. Since they share cholesterol as a common precursor, there are structural similarities among the sex hormones progesterone, estradiol, and testosterone. In the body, much of the circulating progesterone is bound to albumin, corticosteroid binding hormone (CBH) and sex hormone binding globulin (SHBG). As such, a large portion of the progesterone in an individual is bound, not free. This is why many commercial testing platforms include reagents to release progesterone, and other steroid hormones, from the proteins that bind them in the blood.

Progesterone range:

- Female (pre-ovulation): less than 1 ng/mL
- Female (mid-cycle): 5 to 20 ng/mL
- Male: less than 1 ng/mL
- Postmenopausal: less than 1 ng/mL
- Pregnancy 1st trimester: 11.2-90.0 ng/mL
- Pregnancy 2nd trimester: 25.6-89.4 ng/mL
- Pregnancy 3rd trimester: 48.4-42.5 ng/mL
- An ovulating female is generally expected to show progesterone serum levels from 5-10ng/mL (http://www.fertilityplus.org/faq/hormonelevels.html).

2. Assay Specifications (Including LLOQ and ULOQ)

The assay is designed to detect progesterone in buffer, human whole blood, plasma, and serum. The assay has a reportable range of 100 – 0.3ng/mL, in the above mentioned matrices. The assay is specific for progesterone.

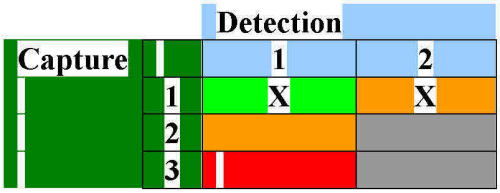
3. Reference Assays

Chosen Reference ELISA Kit
Progesterone ELISA
IBL America distributed by Fitzgerald
Catalog Number: 55R-RE52231
Lot Number: 23K069-2

II) Assay Optimization

4. Antibody Screening Set Summary

Three antibodies were biotinylated and tested with the best candidate detection conjugate. The best overall capture antibody was also tested with a second detection conjugate. Only one good pair was found: capture 1 and detection 1. Detection 2 gave poor modulation, high CVs, and lower top/bottom signal.



Number of capture antibodies tested : 3
Number of detection reagents tested: 2
Total number of capture and detection pairs tested: 4

X Expected good pair
No Modulation
Modulation but background or other problem
Modulation, good candidate pair
Not tested

5. Cross Reactivity and Interference

As part of the current assay development program, six point curves for each of the estradiol, follicle stimulating hormone (FSH), luteinizing hormone (LH), and human choriogonadotropin (hCG) analytes were prepared and tested on the progesterone assay to look for potential **cross reactivity**. These analytes were chosen because they might be multiplexed. Analytes were tested at levels extending from the current low range of the assays out to higher than the current in house assay high calibrators (at least 3 fold higher for all assays except the FSH assay). The tested calibrators for the LH, FSH, hCG, and estradiol assays all came out as OORL and showed no modulation, indicating that the progesterone assay does not respond to these analytes and is in fact specific for progesterone. Please note that there are plans to test additional cross reactants chosen and tested based on structural and functional similarities to progesterone, as is done with standard commercial kits. Examples of cross reactants tested on the chosen reference ELISA from IBL America are as follows: testosterone, estriol, corticosterone, 11-desoxycorticosterone, and pregnenolone.

Summary of Results for Testing Estradiol and FSH Calibrators on the Theranos Progesterone Assay

Test Solutions	Analyte Level	Mean RLUs	Mean Calc Conc (ng/mL)	Assay Result
Progesterone 0ng/mL)	0.000	47945	0.01	OORL (Out of Range Low)
Estradiol (ng/mL)	30.0	57232	0.00	OORL
	6.0	56363	0.00	OORL
	1.2	47163	0.01	OORL
	0.2	42463	0.01	OORL
	0.0	44978	0.01	OORL
	0.0	45537	0.01	OORL
FSH (mIU/mL)	270.0	55947	0.00	OORL
	67.5	49357	0.01	OORL
	16.6	36571	0.02	OORL
	4.2	46319	0.01	OORL
	1.1	45053	0.01	OORL
	0.3	42470	0.01	OORL

Summary of Results for Testing LH and FSH Calibrators on the Theranos Progesterone Assay

Test Solutions	Analyte Level	Mean RLUs	Mean Calc Conc (ng/mL)	Assay Result
LH (ng/mL)	60.0	42536	0.01	OORL (Out of Range Low)
	20.0	49955	0.01	OORL
	6.7	50680	0.01	OORL
	2.2	54891	0.01	OORL
	0.7	49892	0.01	OORL
	0.2	39231	0.02	OORL
hCG (mIU/mL)	6000.0	48265	0.01	OORL
	1200.0	49771	0.01	OORL
	240.0	43577	0.01	OORL
	48.0	50312	0.01	OORL
	9.6	55270	0.01	OORL
	1.9	49568	0.01	OORL

The assay development program also required testing to see how the presence in sample of other fertility related analytes might affect progesterone assay results. To test this, 10x concentrated progesterone solutions were prepared at three different levels and then used to create the following analyte solution sets: progesterone only calibrators (2 sets for 2 experimentation rounds), progesterone calibrators with 30ng/mL of estradiol spiked into all three progesterone solution levels, progesterone calibrators with 6000mIU/mL of hCG spiked into all three progesterone solution levels, progesterone calibrators with 900mIU/mL of FSH spiked into all three progesterone solution levels, and progesterone calibrators with 600ng/mL of LH spiked into all three progesterone solution levels. Solutions were tested on the Theranos progesterone assay and the results were analyzed for analyte recovery. The only analyte to show potential interference was estradiol when tested with progesterone levels at ~11ng/mL. However, significant interference in actual sample testing is not expected as the tested estradiol spike here was 30ng/mL, 15x higher

than the highest calibrator for the Theranos estradiol assay. All other analytes did not show significant interference, as defined by a change of more than 10% from the target progesterone concentration.

Summary Tables of Interference Testing Data

[Progesterone] ng/mL	Interfering Substance and Tested Concentration	Mean RLUs	Signal %CV	Mean Calc Conc (ng/mL)	Concentration %CV	% Recovery
99.8	N/A	274	18.0	99.8	13.2	[100]
60.3	N/A	506	4.5	60.3	3.8	[100]
11.1	N/A	2296	15.4	11.1	12.5	[100]
99.8	30ng/mL Estradiol	317	13.6	96.0	17.2	96
60.3	30ng/mL Estradiol	583	10.9	53.7	9.1	89
11.1	30ng/mL Estradiol	2029	12.3	15.3	9.9	138
105.9	N/A	250	9.2	105.9	7.2	[100]
53.8	N/A	582	11.8	53.8	9.9	[100]
13.1	N/A	2189	16.6	13.1	22.2	[100]
105.9	900mIU/mL FSH	267	13.3	101.2	9.9	96
53.8	900mIU/mL FSH	593	38.3	40.5	0.8	75
13.1	900mIU/mL FSH	2036	10.4	14.3	14.1	109
105.9	6000mIU/mL of hCG	272	11.9	99.6	9.2	94
53.8	6000mIU/mL of hCG	544	5.6	56.8	4.8	106
13.1	6000mIU/mL of hCG	2129	12.4	13.5	16.6	103
105.9	600ng/mL LH	279	14.9	108.2	20.9	102
53.8	600ng/mL LH	599	16.7	52.9	13.9	98

6. Whole Blood and Plasma Screen

Blood was obtained from a blood bank and the whole blood and the plasma derived from the blood were measured in the Theranos System. The table below provides a summary of the results. Please note that some of the samples have progesterone concentrations near the limit of sensitivity for this assay, as they are male blood samples. Testing was done over four lots of tips and three days of testing.

Patient Info		Whole Blood [Calc.] (ng/mL)	Plasma [Calc.] (ng/mL)	% (Plasma Calc Conc/ Blood Calc Conc)
Date	Tube #			
12/4/2009	1	0.27	0.34	125
12/4/2009	2	1.47	1.50	102
12/4/2009	3	0.60	0.53	88
12/4/2009	4	1.43	1.56	109
12/9/2009	2	0.44	0.49	112
12/30/2009	3	0.78	0.52	66
12/30/2009	1	0.46	0.42	92
12/30/2009	2	0.37	0.35	95
12/30/2009	3	0.56	0.59	107
12/30/2009	4	0.15	0.17	118

7. **Capture Titration, Protocol Comparison, and Surface Optimization**

The original capture screening was done using the avidin biotin binding system but results suggested that this chemistry was not providing a consistent surface for the assay, evidenced by poor concentration CVs. This conclusion was reached testing across multiple protocols, reagent concentrations, and assay configurations. To solve the problem, alternative chemistries were tested. Anti-biotin and goat anti-mouse IgG were tested as replacements for avidin. On the goat anti-mouse IgG surface, capture was tested raw (with no conjugation). The goat anti-mouse IgG surface outperformed the anti-biotin and avidin surfaces so the goat anti-mouse IgG chemistry base with raw capture antibody was adopted as the chosen chemistry. Below is sample data of avidin vs goat anti-mouse IgG side by side.

Avidin vs Anti-Mouse IgG Surface Testing

Calibration Range: 60.06 – 0 ng/mL.

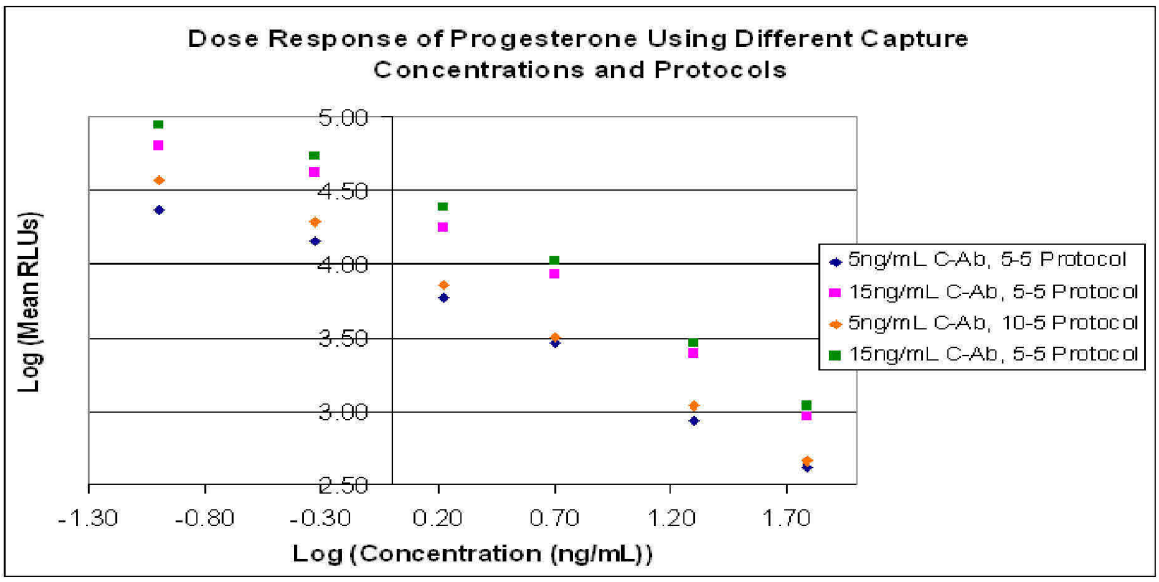
Chemistry Base	20ug/mL U-Avid	50ug/mL Anti-Mouse IgG
End Capture Conditions	50ng/mL biotinylated prog c-ab +10ug/mL bio-IgG	15ng/mL raw prog c-ab
Calibration Verification Equation	y = 0.9372x + 0.4638 R2 = 0.9973	y = 0.9261x + 0.2832 R2 = 0.9997
S/B_Std 6/1	41.89	95.01
S/B_Std 6/5	1.51	1.54
Avg Signal CV	22.4	9.5
Avg Concentration CV	31.6	9.3
Avg Ratio	2.25	2.70
Avg stdev	19082	19899

The goat anti-mouse IgG surface showed higher top/bottom ratio, lower CVs, and better low end differentiation than the avidin surface when directly compared. Since the goat anti-mouse IgG with un-conjugated capture yielded superior results as a first approximation without the need for extensive optimization it is the chosen chemistry combination. However, it if becomes necessary, it is likely that the avidin surface can be made to produce a viable progesterone assay with acceptable CVs. To achieve that goal, biotinylated goat anti-mouse IgG bound to avidin would be used as the base, allowing for the capture to remain un-conjugated. Additional rounds of testing would also be completed for the standard avidin and biotinylated capture combination but re-optimizing for the current co-incubation form of the assay (changing timing, dilutions, etc).

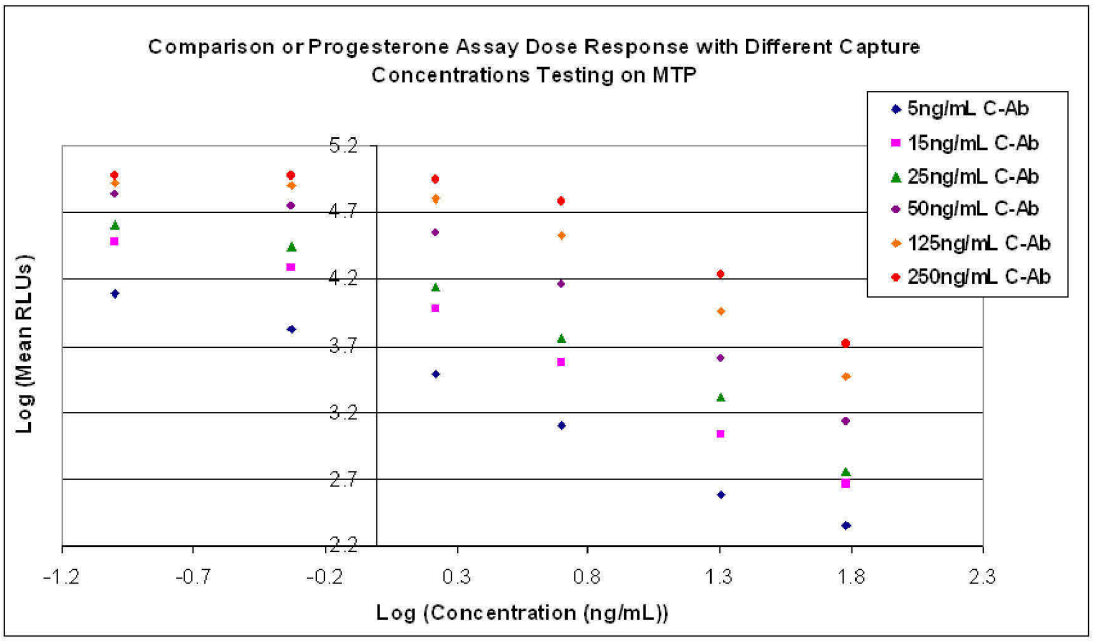
- **Capture Antibody Titration and Protocol Testing on Goat Anti-Mouse IgG Surface**

Capture antibody titration on the most recent platform and several others showed that lower capture concentrations perform the best. Having extensively titrated the capture antibody on previous rounds of testing, only two levels were tested here on the Theranos system: 15 and 25ng/mL.

Protocol	**10_5**	**10_5**	**5_5**	**5_5**
Capture Concentration	**5ng/mL**	**15ng/mL**	**5ng/mL**	**15ng/mL**
S/B_Std 6/1	82.19	80.95	56.19	68.42
S/B_Std 6/5	1.96	1.64	1.62	1.53
Avg Signal % CV	8.4	6.8	8.1	6.1
Avg Conc % CV	11.9	11.0	9.2	10.0
Avg Ratio	2.44	2.49	2.31	2.42
Avg stdev	1546	3699	1718	2472



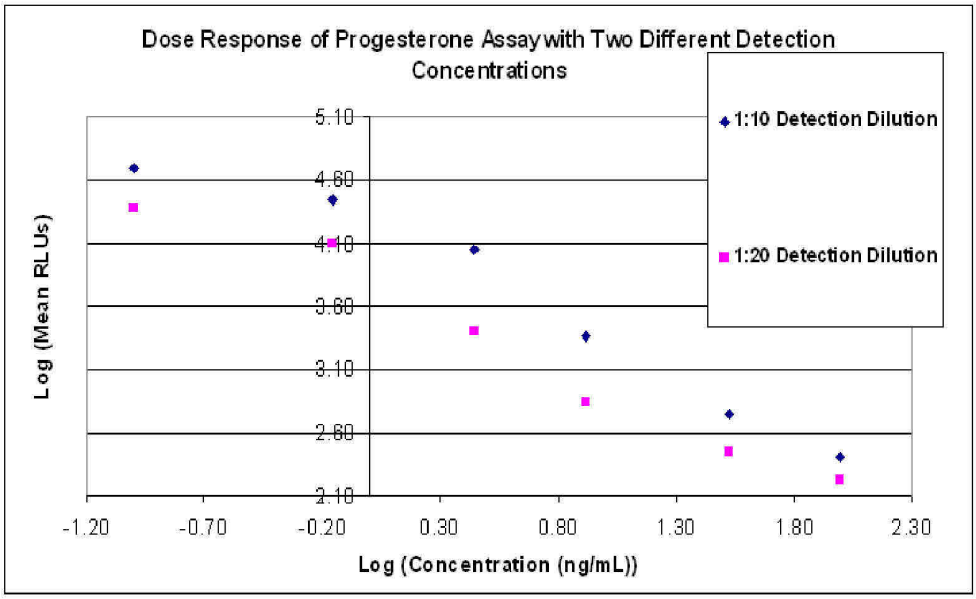
Conclusion: The chosen conditions from testing were the 5_5 protocol using 15ng/mL of capture. This combination gave the best overall combination of low end differentiation, signal and concentration CVs, and modulation. And although it did not give the highest overall top/bottom ratio, the ratio obtained was sufficient. Thus the 5_5 protocol is the chosen protocol for the Theranos progesterone assay for the reasons stated above, because it gives good results in the shortest tested time, and because the estradiol assay favors this protocol. Discussion: Note that the capture concentration used here is low relative to that typically used in assays for protein biomarkers (eg 20 ug/mL). This is partially due to the fact that the standard protein biomarker assays are sandwich assays and this is a competitive assay. In competitive assays for small molecules, such as we have chosen, we cannot use such high reagent concentrations because the antibody concentration must match the analyte concentration to obtain any modulation in the desired analyte range. For information only, please see the data below from titration of the capture antibody on a micro-titer plate during initial testing of the goat anti-mouse IgG and raw capture configuration. With increased capture, the top/bottom ratio became poorer and concentrations in the low end became further off target.



8. Detection Conjugate Titration

The detection conjugate was tested at end dilutions of 1:10 and 1:20, with the reagent being loaded either neat or 2x diluted in stabilizer and the system performing a 1:10 dilution during the protocol (as the assay involves co-incubation of sample and detection on a coated surface). The detection conjugate for this assay is progesterone conjugated to alkaline phosphatase and the reagent is supplied neat with no stated concentration. As such, the tested solutions here are listed in terms of dilution from the neat detection reagent, another difference from standard protein biomarker assays.

Detection Dilution From Neat	**1:10**	**1:20**
S/B_Std 6/1	190.90	142.73
S/B_Std 6/5	1.78	1.90
Avg Signal CV	4.5	9.0
Avg Concentration CV	7.0	14.9
Avg Ratio	3.07	2.93



Conclusion: The 1:10 dilution gave the lowest signal and concentration CVs and highest top/bottom ratio so it is the current chosen dilution. However, the 1:20 could be a future option if needed since it shows similar modulation and low end differentiation. CVs would just need to be improved. As is the case for the capture antibody, in competitive immunoassays the hapten labeled detector reagent concentration must be matched to that of the analyte.

9. Buffer Effects: Testing Different Sample Diluents

Several different sample diluents were tested to address some of the needs of the assay. Because progesterone binds to albumin and several other proteins in blood low BSA sample diluent was tested with and without a steroid displacing reagent, 8-anilino-naphthalene sulfonic acid (ANS) was tested here. Because the chosen capture concentration is low (see experiments below) diluent with added goat IgG was also tested as a means to improve the performance of the assay. The best overall result came from the low BSA buffer with the added goat IgG which improved top/bottom signal and modulation. Adding the ANS caused significant increase to concentration CVs and dropped the top/bottom ratio by more than half. The chosen sample diluent based on testing was the low BSA diluent + goat IgG (0.03% BSA + 500ug/mL goat IgG + 0.05% anti-microbial in TBS). Testing was done in the analyte range from 99.8 – 0.11ng/mL of progesterone using a six point serum curve in duplicate.

Summary Table of Diluent Testing Results

Sample Diluent	Low BSA + IgG Buffer	Low BSA Buffer	Low BSA Buffer + 2mM ANS
Calibration Verification Eqn	y = 1.0324x - 0.5137 R2 = 0.9969	y = 1.0385x - 0.5671 R2 = 0.9982	y = 1.1204x - 1.3819 R2 = 0.9875
Top/Bottom Signal	80.37	59.73	29.52
S/B_Std 6/5	1.80	1.42	1.19
Avg % Signal CV	4.7	3.3	4.7
Avg % Concentration CV	6.3	3.7	12.4
Avg Ratio	2.47	2.46	2.10

10. Precision and CV Test

For precision testing, an 8 point standard curve of serum calibrators was run across three lots of reagents. The results were combined and analyzed as a single standard curve with coefficients of variation (CV) being determined. Samples were assayed in replicate (N = 2 per test solution) on multiple instruments (N = 2 per solution) across the entire range of the assay for each lot of reagents (end total of 6 tips per solution tested).

Summary

Average Inter-Lot Signal CV	8.9 %
Average Inter-Lot Concentration CV	13.8 %
Average Intra-Lot Signal CV	7.4 %
Average Intra-Lot Concentration CV	11.4 %

Total Signal CVs for 3 Reagent Lots

[Progesterone] ng/mL	Mean RLUs	StDev	CV %
62.3	634	56.4	8.9
48.5	839	75.4	9.0
37.1	1151	122.9	10.7
11.3	3022	389.6	12.9
4.4	5640	494.7	8.8
1.5	13618	806.4	5.9
0.8	18526	1427.0	7.7
0.1	33525	2341.0	7.0
Avg Total Signal CV %	8.9		

Total Concentration CVs for 3 Reagent Lots

[Progesterone] ng/mL	Mean Calc Conc (ng/mL)	StDev	CV %
62.3	72.5	4.71	6.5
48.5	47.2	5.74	12.2
37.1	31.8	4.15	13.0
11.3	11.5	1.66	14.4
4.4	5.6	0.67	11.9
1.5	1.4	0.17	12.3
0.8	0.7	0.09	14.1
0.1	0.1	0.03	26.1
Avg Total Concentration CV %	13.8		

Intra Lot Signal CVs for 3 Reagent Lots

[Progesterone] ng/mL	Lot 1 % Signal CV Intra	Lot 2 % Signal CV Intra	Lot 3 % Signal CV Intra
62.3	5.1	15.5	1.8
48.5	6.6	6.8	7.0
37.1	2.8	5.1	9.1
11.3	15.0	9.7	10.8
4.4	7.3	4.6	13.6
1.5	5.3	4.4	7.2
0.8	4.9	11.9	4.1
0.1	4.6	9.1	5.0
Average Intra Signal CV by lot	6.5	8.4	7.3
		Overall Average Intra Signal CV	7.4

Intra Lot Concentration CVs for 3 Reagent Lots

[Progesterone] ng/mL	Lot 1 % Concentration CV Intra	
62.3	7.9	
48.5	9.8	
37.1	3.6	
11.3	15.1	
4.4	9.4	
1.5	11.1	
0.8	12.0	
0.1	15.1	
Average Intra Conc CV by lot	9.8	
Overall Average Intra Lot Conc CV		11.4

One serum solution in the mid range of the assay (25.135 ng/mL) was assayed in a total of 24 cartridges on 24 different instruments to determine the mid-range coefficient of variation (CV).

Summary
Total Signal CV (any cartridge, any instrument): 8 %
Total Concentration CV (any cartridge, any instrument): 7 %

Inter and Intra-Cartridge Concentration CVs at 25.135ng/mL

Cartridge #	Mean Calculated Conc (ng/mL)	StDev	CV %
1	23.5	0.6	2.5
2	22.8	0.0	0.0
3	23.0	2.5	10.7
4	24.0	1.5	6.1
5	22.3	0.1	0.3
6	22.6	0.4	1.6
7	25.9	1.7	6.6
8	20.9	0.6	3.1
9	24.6	3.0	12.2
10	24.3	1.6	6.8
11	22.7	0.5	2.1
12	20.9	1.0	5.0
13	25.1	0.0	0.2
14	24.6	0.7	2.8
15	21.5	0.2	0.8
16	25.5	0.2	0.7
17	24.1	0.7	3.0
18	22.7	0.4	1.9
19	21.4	2.1	9.7
20	23.7	0.2	0.7
21	22.1	1.2	5.6
22	23.7	0.2	0.9
23	24.0	0.6	2.5
24	23.3	2.3	9.7
INTRA Cartridge CV% AVG			4.0

Summary of Total Concentration % CV

Mean Calculated Concentration (ng/mL)	STDev	% Concentration CV
23.3	1.6	7.0

%Recovery Based on Average

93

Calculated Concentration Results Range: 21-26ng/mL

Inter and Intra-Cartridge Signal CVs at 25.135ng/mL

Cartridge #	Mean RLUs	StDev	CV %
1	1821	53	3
2	1880	0	0
3	1877	233	12
4	1777	124	7
5	1930	6	0
6	1905	36	2
7	1629	120	7
8	2084	78	4
9	1742	242	14
10	1755	136	8
11	1895	46	2
12	2088	126	6
13	1683	3	0
14	1727	55	3
15	2015	20	1
16	1657	13	1
17	1765	61	3
18	1895	41	2
19	2041	237	12
20	1801	15	1
21	1957	131	7
22	1799	19	1
23	1776	50	3
24	1844	207	11
INTRA Cartridge CV% AVG			4.6

Summary of Total Signal % CV

Mean RLUs	STDev	% Signal CV
1847	151	8.2

11. Calibrator Comparison

To test the chosen Theranos progesterone analyte stock and create some in house standards for use, the analyte was used spiked into bulk serum (previously tested on the IBL kit to determine endogenous analyte concentration) to create a 10 point calibration curve and the calibrators were

frozen. The calibrators were then thawed and tested on the IBL America kit for recovery. The top calibrators showed recovery close to 100% suggesting that the in house analyte stock has activity on par with the IBL kit materials, our chosen reference kit. The lower concentrations showed recovery that was more than 20% off target. Those concentrations seem to be different due to different sensitivities in that range between Theranos and the IBL America kit. The range of analyte levels where the kit and Theranos differ seems to be ~6ng/mL – 0.5ng/mL, calculating from nominal. The kit sees the Theranos calibrators as low there and the IBL calibrators around that range to be high (see next section). It is possible that in that range the two platforms are responding differently to the interactions between progesterone and the various proteins in sample.

Nominal Concentration (ng/mL)	IBL/Fitz Calculated Concentration (ng/mL)	% Recovery
70.6	62.3	88
47.1	48.5	103
35.4	37.1	105
11.9	11.3	95
6.0	4.4	74
2.1	1.5	71
1.1	0.8	69
0.5	0.3	71
0.2	0.2	106
0.1	0.1	97

The IBL America Progesterone ELISA Kit standards were tested in duplicate on the current Theranos progesterone assay platform to look at recovery. Since the Theranos system calibrators were also tested on the IBL kit, analysis was done both with the in house calibrators assigned the kit determined calculated concentrations, and with the in house calibrators assigned at nominal concentrations based on mass/unit volume. When the system was calibrated relative to the kit, Theranos saw the 40, 15, and 1.25ng/mL calibrators to within 20% of the target but saw the 5 and 2.4ng/mL calibrators as high. When the system was calibrated based on mass/unit volume, only the 40 and 15ng/mL calibrators were seem to within 20% of the target value. The results confirm that there are cross platform differences in calculated results in the range from roughly 6-0.5ng/mL.

Summary Table of Results Calibrating Relative to the IBL Kit

Sample #	Theranos Calc Conc (ng/mL)	IBL Calc Conc (ng/mL)	Theranos % Conc CV	% Recovery
IBL Calibrator 6 (40ng/mL)	38.3	40.7	**10.1**	94
IBL Calibrator 5 (15ng/mL)	17.3	14.5	**12.0**	119
IBL Calibrator 4 (5ng/mL)	6.8	4.8	**3.5**	141
IBL Calibrator 3 (2.5ng/mL)	3.4	2.4	**9.4**	142
IBL Calibrator 2 (1.25ng/mL)	1.4	1.3	**6.5**	107
IBL Calibrator 1 (0.3ng/mL)	0.1	0.3	**32.8**	20

Summary Table of Results Calibrating on Mass/Unit Volume

Sample #	Theranos Calc Conc (ng/mL)	IBL Calc Conc (ng/mL)	Theranos % Conc CV	% Recovery
IBL Calibrator 6 (40ng/mL)	37.0	40.6	**11.9**	91
IBL Calibrator 5 (15ng/mL)	16.4	14.5	**10.1**	113
IBL Calibrator 4 (5ng/mL)	8.4	4.8	**2.4**	174
IBL Calibrator 3 (2/5ng/mL)	4.9	2.4	**8.0**	205
IBL Calibrator 2 (1.25ng/mL)	2.1	1.3	**6.8**	160
IBL Calibrator 1 (0.3ng/mL)	0.0	0.3	**43.2**	16

12. Dilution Linearity

For each test, two clinical samples- one high and one low – were mixed together to test for dilution linearity. The nominal concentrations of the neat samples were set at the Theranos calculated concentration and those values were used to calculate the expected concentrations for the serial dilutions. The test solutions for the Theranos system consisted of the neat high and low samples and several serial dilutions prepared from those sample. The concentrations of the serial dilutions were calculated based on the ratios of the low and high sample used to create them and the nominal concentrations of the low and high samples. The data presented here is from two different days of testing and shows results for 3 sample pairs. Samples showed fairly linear recovery along the relevant range.

The following equation was used to determine the recovery percentage: 100*(calculated concentration/expected concentration). Except for the neat high and low samples which were set at 100% recovery by definition.

Experiment #1: Internal Samples #43 (pregnant female) and M3 (male)

Nominal [progesterone] ng/ml in sample	Dilution from Neat High Sample	Calculated [progesterone] ng/ml in sample	% Recovery
29.1	1X (Neat Sample #43)	29.12	N/A
11.9	2.5X	13.25	112
6.1	5X	6.74	110
3.3	10X	3.48	107
1.8	20X	2.09	115
0.4	N/A (Neat M3)	0.37	N/A
		Avg % Recovery	111

Experiment #2: Internal Samples #4 (pregnant female) and M37 (male)

Nominal [progesterone] ng/ml in sample	Dilution from Neat High Sample	Calculated [progesterone] ng/ml in sample	% Recovery
11.71	1X (Neat Sample #4)	11.71	[100]
6.13	2X	5.86	96
3.34	4X	2.97	89
1.95	8X	1.85	95
1.25	16X	1.49	119
0.55	N/A (Neat M37)	0.55	[100]
		Avg % Recovery	100

Experiment #3: Internal Samples #9 (pregnant female) and M3 (male)

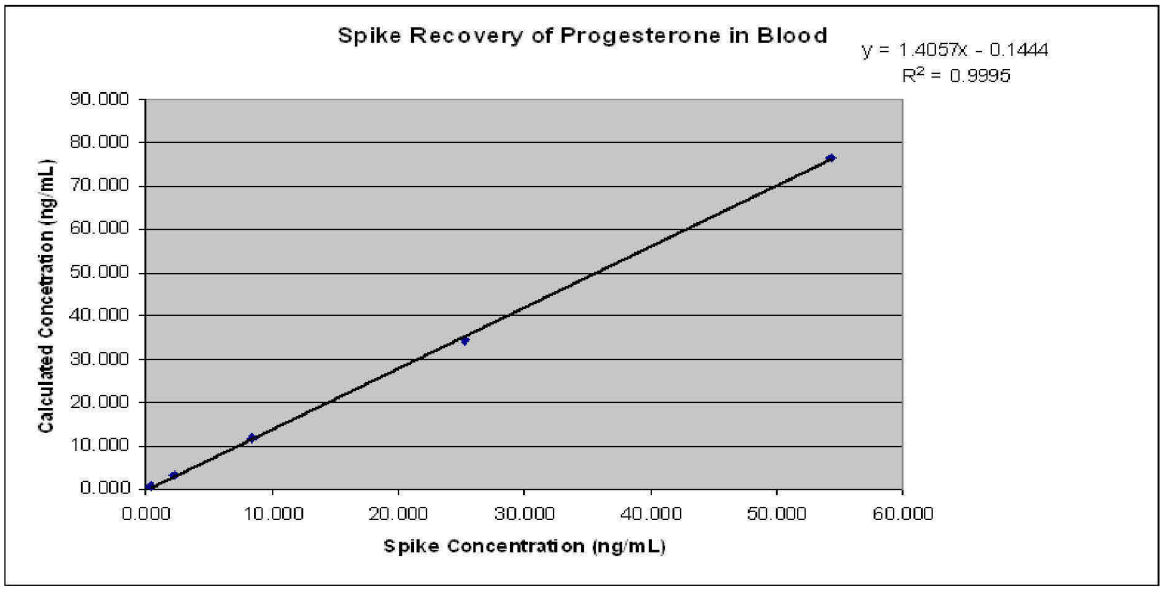
Nominal [progesterone] ng/ml in sample	Dilution from Neat High Sample	Calculated [progesterone] ng/ml in sample	% Recovery
31.67	1X (Neat Sample #9)	31.67	[100]
16.15	2X	18.29	113
8.38	4X	8.68	103
4.50	8X	3.66	81
2.56	16X	2.21	86
0.62	N/A (Neat M38)	0.62	[100]
		Avg % Recovery	96

13. Recovery in Whole Blood and Plasma and Hematocrit Effect

10X concentrated frozen progesterone assay buffer calibrators were directly spiked into whole blood or plasma to give in sample levels across the relevant range. These solutions were then tested on the Theranos system for analyte recovery. The plasma gave essentially 100% recovery and the blood gave elevated recovery, ~144% for the sited experiment below. Ongoing testing is being done to devise a way to calibrate out the difference between directly spiked plasma and whole blood (i.e. to compensate for the difference between blood and plasma). The bioinformatics team is currently processing data to derive a potential correcting equation and we always have the option of calibrating in whole blood. Please see the appendix at the end of this document for initial attempts at correcting for high progesterone recovery in whole blood.

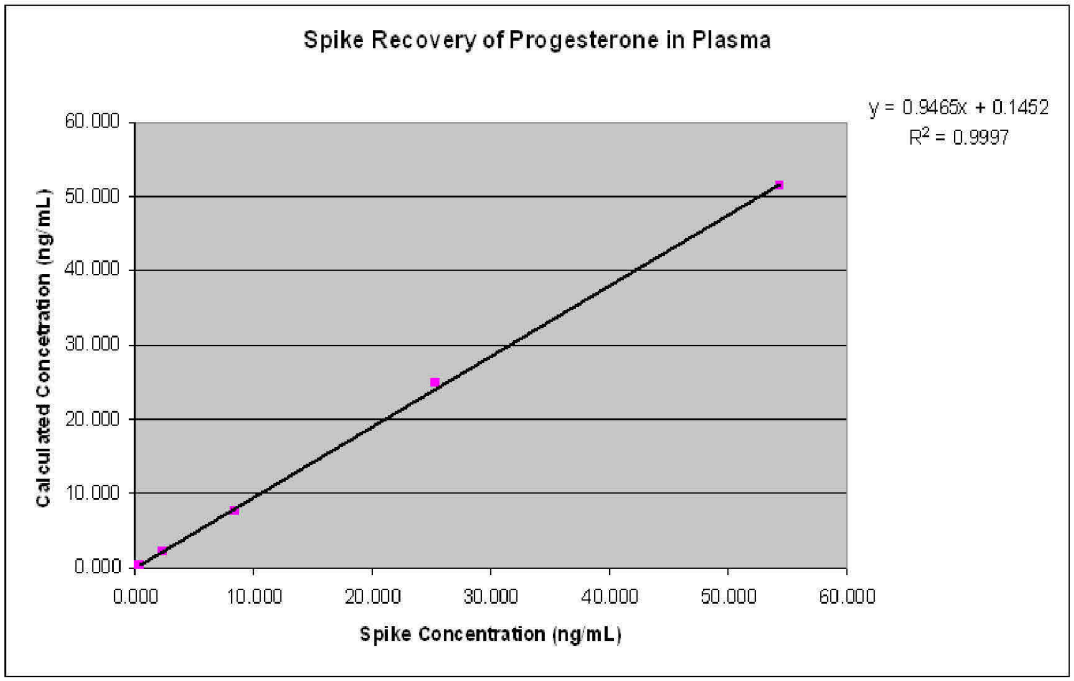
Directly Spiked Whole Blood Data

Spiked [Progesterone] ng/mL	Recovered Conc (ng/mL)	Concentration CV %	% Recovery
54.4	76.8	5.0	141
25.3	34.3	8.6	135
8.4	11.9	6.2	142
2.3	3.1	6.4	139
0.3	0.7	13.3	204
0.0	0.0	30.2	N/A

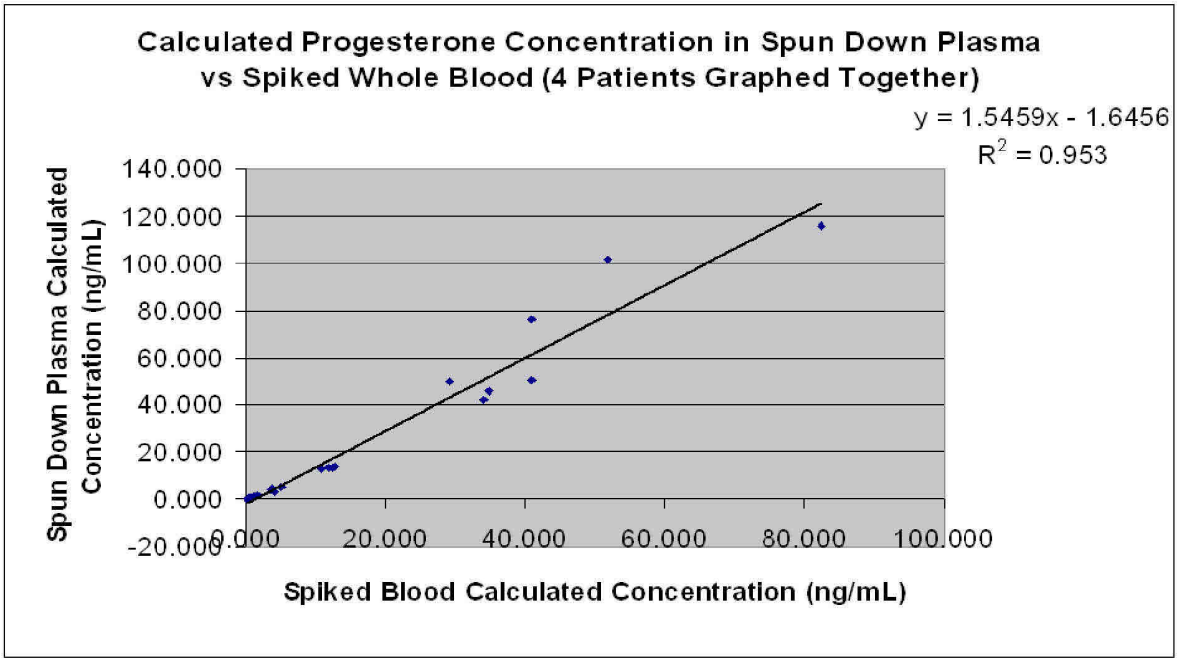


Directly Spiked Plasma Data

Spiked [Progesterone] ng/mL	Recovered Conc (ng/mL)	Concentration CV %	% Recovery
54.4	51.3	12.9	94
25.3	24.8	1.3	98
8.4	7.8	13.3	93
2.3	2.2	15.1	96
0.3	0.5	8.2	141
0.0	0.0	14.1	N/A



To look at hematocrit effect, 10X calibrators at five levels were also spiked into whole blood for four patients and tested along side the spun down plasma from those blood solutions on the Theranos progesterone assay. Zero solutions of each matrix were also run. When compared, the spun down plasma gave recovery at roughly 155% relative to that seen in the whole blood alone.



14. ULOQ and LLOQ

Testing was done to determine the assay upper and lower limits of quantitation. A fresh serum calibrator set was run with concentrations in the range from 51 – 0.11ng/mL of progesterone an extra point above the current range was tested. The results of that testing gave the ULOQ as ~100ng/mL and that the LLOQ as 0.11ng/mL. However, since LLOQ can be variable and the 0.137ng/mL point tested did not meet the criteria for LLOW, the data from several different lots of tips were reviewed and the highest LLOQ found, 0.3ng/mL, was chosen as the LLOQ for this assay to ensure that we do not promise to see results lower than we can on average. 0.3ng/mL was the concentration that consistently met the criteria of concentration CVs at 20% or lower and calculated concentration within 20% of the target, but several lots had LLOQs of 0.16ng/mL so lower LLOQs are possible with this assay.

[Progesterone] ng/mL	[Progesterone] ng/mL	Concentration % CV	% Recovery
101.903	101.903	3.2	105
0.110	0.110	15.2	108

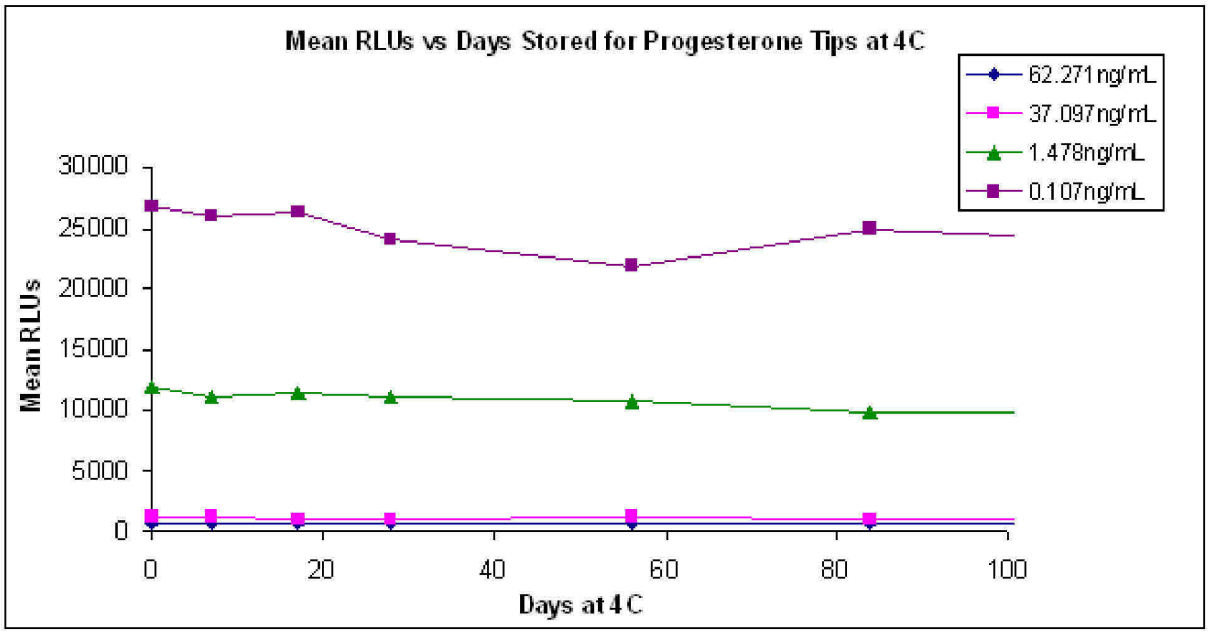
15. Capture Stability

The progesterone test tip capture stability experiment has reached its completion of 24 weeks. For capture stability, coated tips were calibrated using frozen serum calibrators and then they were pouched with desiccant and stored at 4°C and RT. The test schedule for the tips was T = 0 (calibration), 1, 2, 4, 8, 12, and 24 weeks. Four calibrators crossing the range are tested for RT and 4C tips, with 4 tips per storage condition per calibrator tested at each test point. The wet test reagents for stability were those used for calibration of the tips and were set aside for the experiment. At the 12 week test point, the 4C tips showed decent stability with recovery relative

to nominal still generally within 15% of 100 (with some noise at the low end). The room temperature stored tips were more variable in over the course of the stability experiment showed trends that were overall positive. See summary tables below. The 24 week time point showed more noise than the 12 week, with more of the recoveries being greater than 20% off target. It seems likely that the tips are stable for at least 12 weeks but it is harder to say definitively that they are good for 24 weeks. Please note that the 0.107ng/mL point is essentially zero for the assay and represents the endogenous progesterone in the serum used to prepare calibrators. This level is below the stated LLOQ of the assay (0.3ng/mL) and is only included in stability as a point of reference.

Summary Table of % Recovery Relative to Nominal For Progesterone Test Tips Stored at 4°C or RT

Storage Temp	[Progesterone] (ng/mL)	T=0 % Recovery	T= 1 Week % Recovery	T=2 Weeks % Recovery	T=4 Weeks % Recovery	T=8 Weeks % Recovery	T=12 Weeks % Recovery	T=24 Weeks % Recovery
4C	62.271	113	109	106	105	120	114	115
	37.097	84	85	96	101	85	94	129
	1.478	85	99	91	98	105	122	126
	0.107	NA	NA	NA	NA	NA	NA	NA
RT	62.271	113	102	106	110	117	119	120
	37.097	84	104	81	82	81	82	106
	1.478	85	118	143	88	85	143	127
	0.107	NA	NA	NA	NA	NA	NA	NA



16. Matrix Effects

The assay was tested for matrix effects with lipemic and hemolyzed sera. Recovery was highest in lipemic serum, which is not unexpected since progesterone is fat soluble. Recovery was lowest in the hemolyzed serum. The average recovery for lipemic serum was less than 15% different from that in the normal serum and CVs were similar, so lipemic serum does not cause problems. Recovery in hemolyzed serum was 18% lower than recovery in normal serum but showed similar CVs. Hemolyzed samples may give lower readings in the Theranos progesterone assay. Please note that when the same hemolyzed sample was tested (newly spiked) on the chosen reference kit from IBL America, the recovery was also lower than nominal but less consistent along the assay range than the Theranos results were.

Spiked Normal Serum (ProMedDX), Theranos System

[Spiked] ng/mL	Mean RLU	StDev	Signal % CV	[Conc.] ng/mL	Conc % CV	% Recovery Relative to Nominal
54.4	859	51	6.0	44.9	7.5	83
25.3	1484	85	5.8	23.6	5.9	93
8.4	4271	80	1.9	7.4	2.2	88
0.000	21400	1764	8.2	0	14.5	N/A
Avg % Recovery						88

Spiked Lipemic Serum (ProMedDX), Theranos System

[Spiked] ng/mL	Mean RLU	StDev	CV%	[Conc.] ng/mL	Conc % CV	% Recovery Relative to Nominal
54.4	752	47	6.2	50.8	8.8	94
25.3	1229	72	5.9	26.3	6.5	104
8.4	3019	277	9.2	8.3	9.7	98
0	8263	675	8.2	0	13.2	N/A
Avg % Recovery						98

Spiked Hemolyzed Serum (ProMedDX), Theranos System Results

[Spiked] ng/mL	Mean RLU	StDev	CV%	[Conc.] ng/mL	Conc % CV	% Recovery Relative to Nominal
54.4	1032	67	6.5	36.1	7.8	66
25.3	1949	93	4.8	18.0	4.7	71
8.4	4954	662	13.4	6.1	11.2	72
0	40264	1849	4.6	0	16.2	N/A
Avg % Recovery						70

Spiked Hemolyzed Serum (ProMedDX), IBL America Kit Results

[Spiked] ng/mL	O.D. CV%	[Conc.] ng/mL	Conc % CV	% Recovery Relative to Nominal
54.4	4.4	34.618	4.4	64
25.3	14.7	21.534	14.7	85
8.4	12.2	9.140	12.2	109
4.6	5.7	3.168	5.7	68
0	24.9	0.000	24.9	N/A
Avg % Recovery				81

17. Max Range

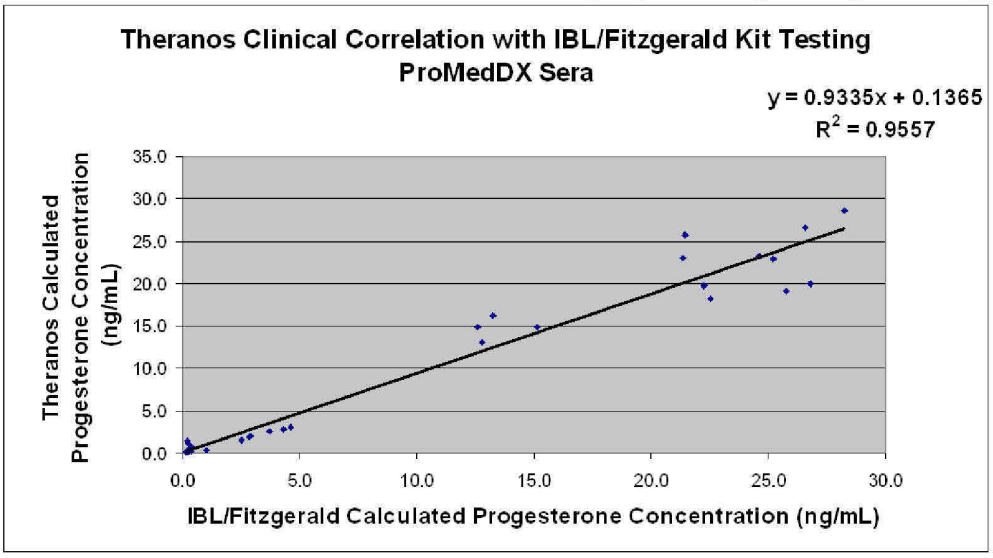
To test the maximum range over which the progesterone assay gives accurate results, progesterone at several levels over the current top calibrated range were spiked directly into into whole blood and plasma and analyzed against a serum calibration curve. The goal was to determine the highest level that can be accurately seen for the progesterone assay using the current calibration range. The testing showed the maximum level to be accurately determined as 100ng/mL, with a calibration up to ~64ng/mL. Results were similar for both tested matrices.

Test Matrix	Spiked [Progesterone] ng/mL	Concentration CV %	Mean Calc Conc (ng/mL)	% Recovery Relative to Nominal
Blood	800.0	6.4	129.0	16
	400.0	14.6	166.8	42
	100.0	15.0	95.2	95
	0.0	15.4	0.2	N/A

Plasma	800.0	11.3	148.5	19
	400.0	13.2	177.2	44
	100.0	7.9	91.1	91
	0.0	15.0	0.2	N/A

18. Assay accuracy Clinical Sample Assay correlation

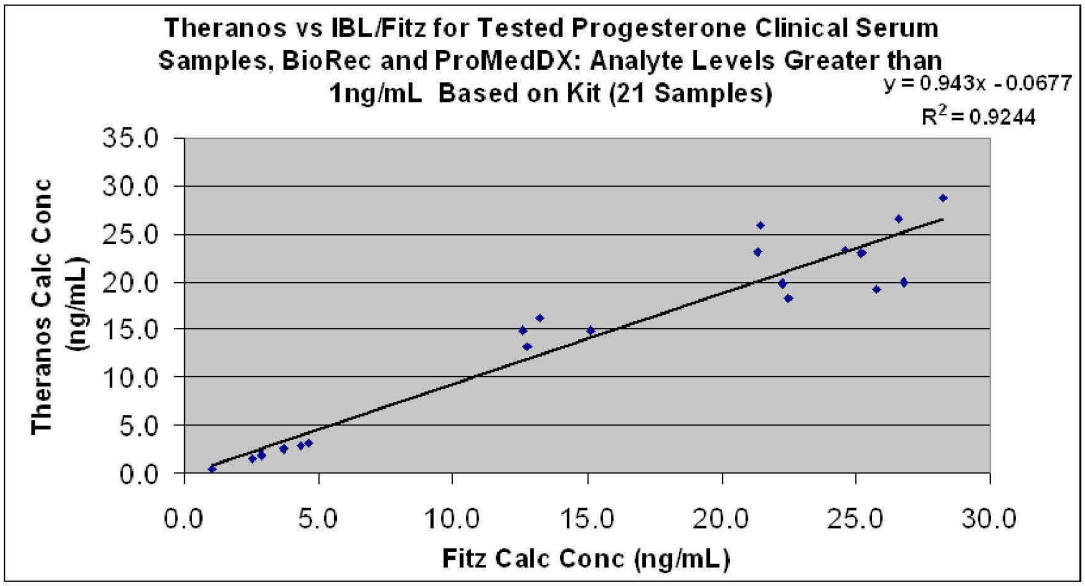
Clinical pregnancy and normal male serum samples obtained from BioReclamation and ProMedDX were run in the Theranos system (calibrated using mass/unit volume starting from stock at an assumed nominal concentration) and the IBL America ELISA (distributed by Fitzgerald). For a total of 32 samples across the range of the assay, correlation was Theranos (y) = 0.335*Reference method (x) - 0.1365; R^2 = 0.9557 (see table below). For the set of 32 samples, the average Theranos system concentration % CV was 11.3. Theranos system conditions were the current best stated in this report, including testing on the 5_5 protocol.



Sample #	Theranos Calc Conc (ng/mL)	Fitzgerald/IBL Calc Conc (ng/mL)	Theranos Conc % CV	%(Theranos Result/IBL Kit Result)	Sample Source
3	18.2	22.5	7.5	81%	BioReclamation
40	19.8	22.3	10.4	89%	BioReclamation
41	20.0	26.8	8.1	75%	BioReclamation
47	19.2	25.8	6.6	74%	BioReclamation
48	23.3	24.6	10.0	95%	BioReclamation
M2	0.4	0.3	4.4	162%	BioReclamation
M3	0.8	0.4	23.3	215%	BioReclamation
1	25.8	21.4	2.0	120%	BioReclamation
4	14.9	15.1	1.2	98%	BioReclamation
5	26.5	26.6	7.0	100%	BioReclamation
6	13.2	12.8	5.6	103%	BioReclamation
44	22.9	25.2	3.0	91%	BioReclamation
45	16.2	13.2	2.4	122%	BioReclamation
46	14.9	12.6	5.7	119%	BioReclamation
M37	1.1	0.3	11.0	441%	BioReclamation
M38	1.4	0.2	16.9	603%	BioReclamation
M39	0.0	0.2	13.5	16%	BioReclamation
M1	0.5	0.3	20.1	177%	BioReclamation
13	0.1	0.2	13.8	70%	ProMedDX
15	0.1	0.3	25.5	48%	ProMedDX
16	0.2	0.4	17.4	63%	ProMedDX
19	1.5	2.5	8.6	60%	ProMedDX
20	2.0	2.9	15.7	69%	ProMedDX
21	3.1	4.6	9.9	68%	ProMedDX
22	2.9	4.3	10.5	66%	ProMedDX
26	2.6	3.7	10.0	70%	ProMedDX
27	1.8	2.9	14.1	64%	ProMedDX
28	0.4	1.0	16.7	36%	ProMedDX
51	28.6	28.2	9.4	101%	ProMedDX
56	23.1	21.4	10.7	108%	ProMedDX
80	0.3	0.2	18.1	190%	ProMedDX
82	0.3	0.2	24.0	109%	ProMedDX

If samples with calculated concentrations less than 1ng/mL based on IBL kit testing are removed from the correlation graph, correlation is Theranos (y) = 0.943*Reference method (x) - 0.0677; R^2 = 0.9244(see table below). For that set of 21 samples, the average Theranos system concentration % CV was 8.3.

Sample #	Theranos Calc Conc (ng/mL)	Fitzgerald/IBL Calc Conc (ng/mL)	Theranos Conc % CV	%(Theranos Result/IBL Kit Result)	Sample Source
3	18.2	22.5	7.5	81%	BioReclamation
40	19.8	22.3	10.4	89%	BioReclamation
41	20.0	26.8	8.1	75%	BioReclamation
47	19.2	25.8	6.6	74%	BioReclamation
48	23.3	24.6	10.0	95%	BioReclamation
1	25.8	21.4	2.0	120%	BioReclamation
4	14.9	15.1	1.2	98%	BioReclamation
5	26.5	26.6	7.0	100%	BioReclamation
6	13.2	12.8	5.6	103%	BioReclamation
44	22.9	25.2	3.0	91%	BioReclamation
45	16.2	13.2	2.4	122%	BioReclamation
46	14.9	12.6	5.7	119%	BioReclamation
19	1.5	2.5	8.6	60%	ProMedDX
20	2.0	2.9	15.7	69%	ProMedDX
21	3.1	4.6	9.9	68%	ProMedDX
22	2.9	4.3	10.5	66%	ProMedDX
26	2.6	3.7	10.0	70%	ProMedDX
27	1.8	2.9	14.1	64%	ProMedDX
28	0.4	1.0	16.7	36%	ProMedDX
51	28.6	28.2	9.4	101%	ProMedDX
56	23.1	21.4	10.7	108%	ProMedDX



19. Conclusions

The current progesterone assay meets the set release criteria for the Theranos development program. The assay yields strong clinical sample correlation with an established commercial kit (from IBL America), gives concentration and signal CVs that are within the acceptable range (generally less than 15%), and gives meaningful results in blood, plasma, and serum. The finished assay represents the first small molecule assay developed on the current Theranos assay system (reader and cartridge) and can serve as a reference for future development of similar assays. It may also serve as a reference for future in house competitive assay development.

Appendix A: Progesterone in Blood and Plasma

As noted earlier in this report, the progesterone assay has been prone to showing recovery greater than 100% when testing spiked into whole blood. The Biomathematics group at Theranos has been working on correction factors to improve the correlation between Theranos assay calculated progesterone results in plasma and whole blood. Using calculated concentration data for spike recovery from directly spiked blood and plasma from the same person across 5 patients, the Kapil was able to generate 2 models that allow for the calculated blood result in the Theranos progesterone assay to be corrected so that the result more closely matches that seen in the plasma. As seen from the data below, using either of the two models generated improves the accuracy of the results but model 2 appears to have a slight advantage. A model such as one of these should be used for conversion between blood and plasma results if a separate calibration in whole blood is not done for the progesterone assay. However, results suggest that recovery might still be noisy in blood and plasma for progesterone so more work will have to be done.

Summary Table of Model 1 Equation and Parameters:

model 1	log10(Y) = p1 + (p2-p1)/(1 + (X/p3)^p4)
p1	-3.254
p2	2.767
p3	1.574
p4	-0.415

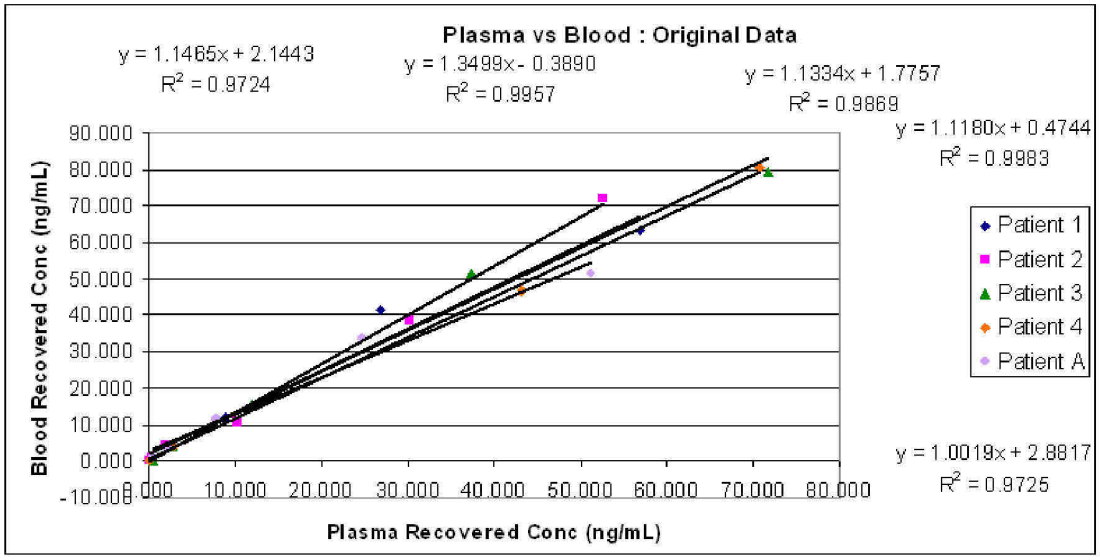
Summary Table of Model 2 Equation and Parameters:

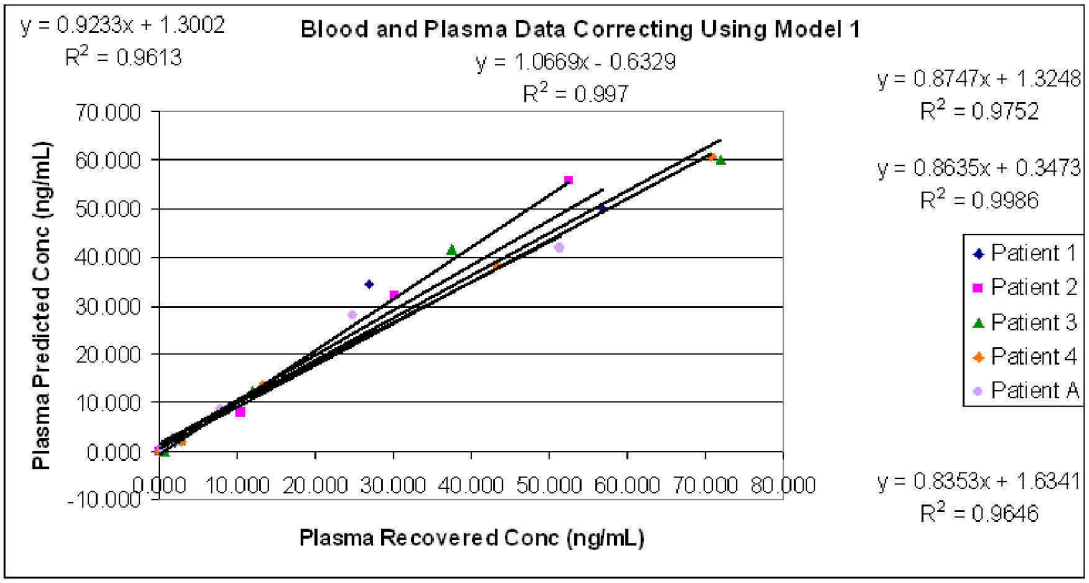
model 2	log10(Y) = p1 + p2 * log10(X) + p3 * log10(X)^2
p1	-0.489
p2	1.429
p3	-0.113

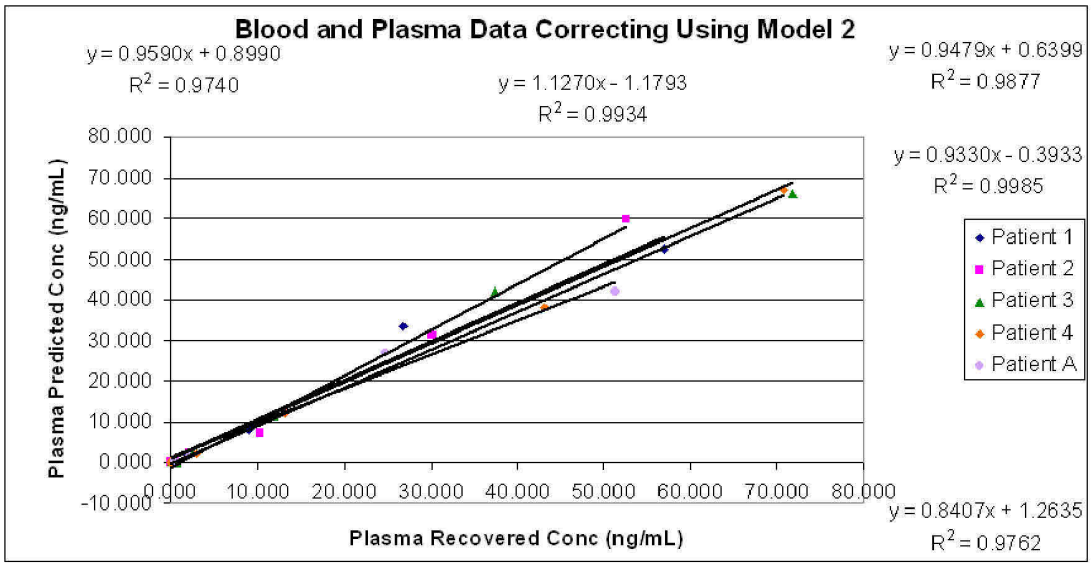
Summary Tables for Model Results and Performance

Patient	Original Blood vs Plasma Eqn	Model 1 Blood vs Plasma Eqn	Model 2 Blood vs Plasma Eqn
1	y = 1.1465x + 2.1443	y = 0.9233x + 1.3002	y = 0.9590x + 0.8990
2	y = 1.3499x - 0.3890	y = 1.0669x - 0.6329	y = 1.1270x - 1.1793
3	= 1.1334x + 1.7757	y = 0.8747x + 1.3248	y = 0.9479x + 0.6399
4	y = 1.1180x + 0.4744	y = 0.8635x + 0.3473	y = 0.9330x - 0.3933
A	y = 1.0019x + 2.8817	y = 0.8353x + 1.6341	y = 0.8407x + 1.2635

Patient	Original Result % Off Target	Model 1 % Off Target	Model 2 % Off Target
1	15	8	4
2	35	7	13
3	13	13	5
4	12	14	7
A	0	16	16
Avg % Off Target	15	12	9







Summary Table of % Progesterone Recovery in Whole Blood with and Without Correction

Note: Values highlighted in yellow are 20% or more off target.

Patient	Spike Level (ng/mL)	Original % (Blood /Plasma)	% (Blood /Plasma After Correction
1	54.353	112	91
1	25.349	154	125
1	8.417	131	104
1	4.633	181	138
1	2.807	192	127
1	0.961	166	93
2	54.353	137	112
2	25.349	127	104
2	8.417	104	83
2	4.633	192	148
2	2.807	156	97
2	0.961	155	65
3	54.353	110	90
3	25.349	135	110
3	8.417	128	103
3	4.633	141	109
3	2.807	159	107
3	0.961	45	20
A	54.353	114	93
A	25.349	108	88
A	8.417	127	102
A	4.633	133	102
A	2.807	156	85

Summary Table of % Progesterone Recovery in Whole Blood with and Without Correction

Patient	Spike Level (ng/mL)	Original % Recovery	% Recovery After Correction
1	54.353	117	96
1	25.349	164	134
1	8.417	139	113
1	4.633	78	64
1	2.807	36	30
1	0.961	45	37
2	54.353	133	109
2	25.349	153	125
2	8.417	127	104
2	4.633	94	77
2	2.807	29	24
2	0.961	23	19
3	54.353	146	120
3	25.349	203	166
3	8.417	187	153
3	4.633	94	77
3	2.807	38	31
3	0.961	7	6
A	54.353	148	122
A	25.349	184	150
A	8.417	200	164
A	4.633	86	71
A	2.807	25	20

Summary Table of % Progesterone Recovery in Plasma

Patient	Spike Level (ng/mL)	% Recovery
1	54.353	105
1	25.349	106
1	8.417	105
1	4.633	39
1	2.807	12
1	0.961	12
2	54.353	97
2	25.349	119
2	8.417	122
2	4.633	46
2	2.807	15
2	0.961	3
3	54.353	132
3	25.349	148
3	8.417	141
3	4.633	58
3	2.807	8
3	0.961	60
A	54.353	130
A	25.349	170
A	8.417	157
A	4.633	63

A	2.807	13