

**To:** Sunny Balwani[sbalwani@theranos.com]  
**From:** Daniel Young  
**Sent:** Mon 8/25/2014 5:02:17 AM  
**Importance:** Normal  
**Subject:** RE: bot experience  
**Received:** Mon 8/25/2014 5:02:16 AM

Beside PT/INR, we are currently working on different issues related to these assays:

- HCG (automated extra dilution to extend dynamic range)
- Testosterone (automated extra dilution to extend dynamic range)
- VBI2 (evaluating comparison to predicate)
- TSH/FT4 (correlation and sensitivity)
- CO2 (CIN device related; new bias corrections being implemented now)
- New reference ranges for glucose, K, CO2 in fingerstick samples

-Daniel

---

**From:** Sunny Balwani  
**Sent:** Sunday, August 24, 2014 9:51 PM  
**To:** Daniel Young  
**Subject:** Re: bot experience

Are there any other assays you have concerns with and if so please send me a list. I can prioritize these over other work.

On Aug 24, 2014, at 9:37 PM, "Daniel Young" <dyoung@theranos.com> wrote:

As I mentioned, I had some concerns a few weeks back about sample stability for PT/INR only when patients are under Coumadin treatment. We created a study plan to evaluate this, and are working on recruiting patients for the study.

I feel that this is the only likely reason for low PT/INR results. Other things to check next are EDTA concentration variability – but we have studied this in the past with normal subjects and found no significant issues. But for patients undergoing treatment, there could be different sensitivities.

-Daniel

---

**From:** Sunny Balwani  
**Sent:** Sunday, August 24, 2014 9:26 PM  
**To:** Daniel Young  
**Subject:** Fwd: bot experience

Daniel. The net net of this seems to suggest that our PT was reporting results too low. Can u plz take a look into this. Thanks.

Begin forwarded message:

**From:** Max Fosque <[mfosque@theranos.com](mailto:mfosque@theranos.com)>

**Date:** August 24, 2014 at 9:17:21 PM PDT

**To:** Sunny Bdwani <[sbdwani@theranos.com](mailto:sbdwani@theranos.com)>

**Cc:** Daniel Young <[dyoung@theranos.com](mailto:dyoung@theranos.com)>, Christian Holmes <[cholmes@theranos.com](mailto:cholmes@theranos.com)>

**Subject:** Re: bot experience

That is correct

On Aug 24, 2014, at 9:12 PM, "Sunny Bdwani" <[sbdwani@theranos.com](mailto:sbdwani@theranos.com)> wrote:

Seems like they ignored the software and collected wrong vau container. However, since sample got here in 24 hours, they were able to redeem it, make a manual human decision and run it on bcsxp. Max. Did I understand this correctly and can us verify in fact this is what happened.

Thx

On Aug 24, 2014, at 9:09 PM, "Daniel Young" <[dyoung@theranos.com](mailto:dyoung@theranos.com)> wrote:

Just to confirm, the correct vau container was collected in this case, correct?

-Daniel

On Aug 24, 2014, at 9:07 PM, "Max Fosque" <[mfosque@theranos.com](mailto:mfosque@theranos.com)> wrote:

I believe 36 hours.

Na nitrate tube was run on BCSXP device just within 24 hr of collection. Stability is 24hr for that method.

Daniel and I will check with Langly on QC

On Aug 24, 2014, at 8:56 PM, "Sunny Bdwani" <[sbdwani@theranos.com](mailto:sbdwani@theranos.com)> wrote:

What is the sample stability for PT on Normandy method? I will speak with Tina about this tomorrow as to why a sample collected at 723am on day 1 is not being processed until 34 hours later.

Daniel can look into the quality checks etc for the first 2 days.

Please check with Langley on #3 specifically and see what method we used for 3<sup>rd</sup> critical high value and the QC for that method.

Thanks.

---

**From:** Max Fosque  
**Sent:** Sunday, August 24, 2014 8:16 PM  
**To:** Daniel Young  
**Cc:** Sunny Bdwani; Christian Holmes  
**Subject:** FW: bot experience  
**Importance:** High

Daniel,

Please see the note below from Tracy, regarding a reported discrepancy in PT/INR results for one of our employees. I've compiled the information I can glean from LIS and am awaiting a response from the field on whether or not the venous sample was frozen. Please let me know if you need anything else for investigation.

Visit 1: 8/05, 7am. Container received at 7.23am, next day. Aliquoted into PIPlate at 5.33pm next day, 34 hours after collection.

PT: 18.4 (High)

INR: 1.5

CIN: 000000000118454

Visit 2: 8/20, 9.40am. Container received at 6.30am, next day. Aliquoted into PIPlate at 11.20am, 25 hours after collection.

PT: 18.9 (High)

INR: 1.6

CIN: 000000000121050

Visit 3: 8/22, 2.50pm. Sod Citrate Vac received 8/23 at 12pm, resulted at 2.15pm next day. Almost exactly 24 hours. I don't believe the sample was frozen but following up to confirm.

PT: 44 (Critical High)

INR: 3.6

<\*(J span>

Both EDTA CIN images look normal.

Thanks,

Max

---

**From:** Tracy Masson

**Sent:** Sunday, August 24, 2014 8:01 PM  
**To:** Sunny Balwani; Christian Holmes; Max Fosque  
**Cc:** Ryan Karpel  
**Subject:** bot experience  
**Importance:** High

Could you please check on these results?  
These are for \_\_\_\_\_, one of our bots.

Thanks,

Tracy

**NOTEWORTHY:**

**On a personal lab testing level, I have been on anticoagulants for about 14 years now. I have been within recommended P/I INR range for about 13 years, prompting the same mg dosage for over a decade.**

**I recently had my standing order switched to Theranos for my P/I INR monitoring. This was the first time I had a CIN draw for my P/I INR. I was surprised when the results came back out of range (too low). My doctor advised me to retest about a week later. The second CIN result was also extremely low and he increased my Coumadin for one dose. This was last week. I have not felt "right" since the one increased dose and also experienced various skin bruising on my legs and arms almost immediately after the one dose increase. I asked for another standing order draw at the end of my shift yesterday. This time I wanted the draw switched from CIN to a venous draw.**

**An error was encountered when switching the draw from finger stick to venous draw. The system prompted a Lavender tube. Knowing this is incorrect for a coagulation test, I called Customer Support and speaking with Stacy, verified that that system had indeed prompted the wrong venipuncture tube.**

**The Phlebotomist, Emily who was performing my draw and I changed the tube in the system and she drew a blue top for a correct P/I INR venipuncture.**

**My doctor just called me because my P/I INR results now show that it is very high. I am to**

skip my dose tonight and retest on Monday.

For testing accuracy, I will be getting both a venipuncture and a CTN draw on Monday to compare results, as this information would be of utmost importance to Theranos and ultimately to the well-being of our patients. I will report when I receive the results on both and hopefully the numbers will correspond. I will also verify that the PT/INR App screen prompts for the correct tube.

Emily documented the system error on her IT=PSC App Log to Ryan Karpel and Bryan K and in her EOS Report to Phx Leaders.

<\*(Jp class=MsoNormal>

Tracy Masson, General Manager Arizona Operations

480-492-9426

PRIVILEGED AND CONFIDENTIAL COMMUNICATION

IMPORTANT \*(J-\*(JThis electronic transmission, and any files transmitted with it are confidential and/or legally privileged information. This information is intended solely for the use of the individual or entity to which it is addressed. Any disclosure, retransmission, reproduction, dissemination or other use of the contents of this information by persons or entities other than the intended recipient is strictly prohibited. If you have received this email in error, please contact us immediately and delete all copies. Please note that any views or opinions presented in this email are solely those of the author and do not necessarily represent those of Theranos, Inc. Finally, before opening or using attachments the recipient should check this email and any attachments for the presence of viruses. Theranos, Inc. accepts no liability for any damage caused by any virus transmitted by this email. Our sole responsibility is limited to resupplying any affected attachments.

Theranos, Inc., 1601 S California Avenue, Palo Alto, CA, 94304

650-838-9292 | [www.theranos.com](http://www.theranos.com)