

Message

From: Sunny Balwani [/O=Theranos Organization/OU=First Administrative Group/CN=Recipients/CN=SBALWANI]
Sent: 8/25/2014 4:48:26 AM
To: Elizabeth Holmes [eholmes@theranos.com]
Subject: Fwd: bot experience

Always another study after the fact.

Begin forwarded message:

From: Daniel Young <dyoung@theranos.com>
Date: August 24, 2014 at 9:37:35 PM PDT
To: Sunny Balwani <sbalwani@theranos.com>
Subject: RE: bot experience

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>
Date: August 24, 2014 at 9:17:21 PM PDT
To: Sunny Balwani <sbalwani@theranos.com>
Cc: Daniel Young <dyoung@theranos.com>, Christian Holmes <cholmes@theranos.com>
Subject: Re: bot experience

That is correct

On Aug 24, 2014, at 9:12 PM, "Sunny Balwani" <sbalwani@theranos.com> wrote:

Seems like they ignored the software and collected wrong vacutainer. 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 we verify in fact this is what happened.

Thx

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

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

-Daniel

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

I believe 36 hours.

Na citrate 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 Balwani" <sbalwani@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 3rd 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 Balwani; 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 PTPlate at 5.33pm next day, 34 hours after collection.
PT: 18.4 (High)
INR: 1.5
CTN:
000000000118454

Visit 2: 8/20, 9.40am.
Container received at 6.30am, next day.
Aliquoted into PTPlate at 11.20am, 25 hours after collection.
PT: 18.9 (High)
INR: 1.6

CTN:
0000000000121050

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

Both EDTA CTN 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
PT/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 PT/INR monitoring. This was the first time I had a CTN draw for my PT/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 CTN 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 CTN 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 PT/INR

venipuncture.

My doctor just called me because my PT/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.**

Tracy Masson, General
Manager Arizona Operations
480-492-9426

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Theranos, Inc., 1601 S
California Avenue, Palo Alto,
CA, 94304
650-838-9292 |
www.theranos.com