

To: Elizabeth Holmes[eholmes@theranos.com]
From: Sunny Balwani
Sent: Sat 4/12/2014 6:00:25 PM
Importance: Normal
Subject: Fwd: PT Plan & Communication
Received: Sat 4/12/2014 6:00:27 PM

Begin forwarded message:

From: Adam Rosendorff <arosendorff@theranos.com>
Date: April 12, 2014 at 10:25:32 AM PDT
To: Sunny Balwani <sbalwani@theranos.com>, Mark Pandori <mpandori@theranos.com>
Subject: RE: PT Plan & Communication

Sunny

I have modified the SOP to reflect our current AAP procedure (minor changes) and added a section on acceptance criteria and corrective actions.

Mark and I will put together a PPT that we can communicate in our CLIA general meeting.

I agree that misconceptions around this need to be dispelled.

Adam

Sent from my Windows Phone

From: Sunny Balwani
Sent: 4/12/2014 10:17 AM
To: Mark Pandori
Cc: Adam Rosendorff
Subject: PT Plan & Communication

Mark.

Per our conversation from this week, I would like a communications plan clearly documented on how we do AAP for PT. The SOP for this has always been in place, but you mentioned you didn't know about this until this week and now that you have read it, you wanted to add few minor clarifying details to this. Please correct me if I misunderstood this.

More importantly though, I want our AAP SOP process in a powerpoint in which this could be easily explained and understood by others in CLIA. Here is why:

Initially because of wrong decisions around vitamin D PT samples from earlier this year, including comments that were made by either CLIA lab management or others in CLIA around our PT process, there is confusion around how PT on our process will be done and should be done. On top of that, Langley went and mailed the initial TSH and FT4 5 patient study runs data to junior technicians in CLIA who don't have the background or the understanding to properly interpret the data. This is now creating a toxic environment and some junior CLIA team members are communicating to people outside CLIA that our PT process is either wrong or not in place, both are inaccurate. This needs to be addressed this week by you and Adam.

Please prepare this powerpoint that explains to the CLIA staff what PT is, how we will do PT and why so we can get the CLIA team on the same page. It is also critical that CLIA lab members who don't understand this come and ask you and Adam for guidance or questions. Creating confusion and miscommunication around CLIA processes and SOPs is not acceptable and I would like for you to mention that in the team meeting and put an end to that.

I am spending a lot of time on CLIA related issues like understanding the FT4 and TSH over-recovery (we will solve this problem in matter of days, we are close), LIS and QC software, process, procedures and support personnel for CLIA and will continue to do so. What I don't want to spend time on and want you and Adam to spend time on are these communication issues. This is a small team and must be tightly managed. If there are problem areas in this team then please let me know in real time.

Please send me this slide deck when ready so I can review this with others in the team, provide feedback and then by end of week or sooner, and then you can meet with CLIA team and go over the deck and answer their questions and put the PT discussion to rest once and for all.

Thanks.