

**To:** Adam Rosendorff[arosendorff@theranos.com]  
**Bcc:** Elizabeth Holmes[eholmes@theranos.com]  
**From:** Sunny Balwani  
**Sent:** Thur 10/9/2014 9:55:46 PM  
**Importance:** Normal  
**Subject:** FW: Please call Dr. Palmer  
**Received:** Thur 10/9/2014 9:55:45 PM  
RE: FW: Physician Call Needed Before 4pm.msg

Adam, we are in the process of responding to the doctor but I wanted to share with you few thoughts on this case:

1. Chinmay and Daniel etc reviewed the tip counts and said they looked good. The spurious result in all likelihood seem to be due to hemolysis, though it is difficult to say if it was above our tolerance limit or not. And, other than that, we do not have evidence of any other analytical failures or anomalies during these runs. the QC and performance of the assay otherwise looks good. initially you suspected that we may have mixed up samples but that is not the case and as far as I know that has never happened in our system. You had sent me an email confirming that there was no issue around sample mix up and in fact there were 2 patients with same name (see attached). we will communicating to the Physician that this was due to hemolysis and offer a redraw. the Patient may be on TST therapy so we will share that with the physician also.
2. We are doing monthly (most cases cases weekly) IQP (AAP) for each assay on Edisons & other devices downstairs. All of this data is 100% on the folders accessible to you as had been agreed upon over 6 months ago. We should take this data and formalize it for you to review and sign off. Langley is not the right person for this as he is barely keeping up with upstairs lab and I want him focused only on upstairs lab. As you may recall, We are doing equivalent AAP on weekly bases on every/most assays. We decided to call it IQP because we are doing it so frequently as AAP was confusing people as to why we are doing AAP on weekly basis (to provide extended oversight). You and Mark had created a PowerPoint for CLIA team and you guys actually had pointed out that doing this weekly just may be too excessive. For now though, we are doing excessive AAP. However, we need to keep this data in the right format and make it part of CLIA folders. I don't think the data is being put in right format but I could be wrong on this and it may be but I will confirm with Nishit. We are only required to do these AAPs once per 4 months as you already know so we have more than enough data to show that we have done this excessively.
3. In addition, as required by our SOPs, there is separate daily QC that is done on all assays and all devices for CLIA and that is already in place for each device and each assay and there is an app that I assume you have been using to view the quality data & Levey-Jennings charts and graphs. if you don't have access to it then please let me know and IT will install it on your computer and Swapna can walk you through it.
4. As you may also know, Chinmay, Daniel, Nishit and myself are monitoring this quality data on almost daily basis. This is not needed for CLIA purposes but for product development and product improvement purposes). I would recommend that if you want to get weekly briefings on this, you setup time with Nishit and Chinmay on the 13 ELISA assays, CBC and Advia assays and I know they will be very happy in walking you thru this. If we ever see any reasons for concern, on daily basis I demand action and this team of leads has been ALWAYS supremely responsive in reacting in real time and addressing and resolving any of these issues. We feel extremely confident of the quality of our lab – more than we ever have been, and more than I am of many devices we acquire from 3<sup>rd</sup> parties – Etimex being a perfect example.
5. In an overwhelming majority of the cases, we see that hemolysis causes issues and the best way is to force redraws. As you know, CLSs have made errors in the past releasing results that shouldn't have been only if they had looked up the sample images. We are modifying software to make it more fool proof. Max pointed out a suggestion by you that we should force CLS to view image of the Nanotainers before they release results which are out of range. I think this is a great idea. We are implementing this asap and will be in production by Monday or Tuesday of next week. This will provide us an additional layer of peace of mind and force CLS to provide additional oversight.
6. Despite all our best efforts, there will be results that are unexpected. However if there are any discrepancies in results, the best is to investigate which is what we always do. In that regard, the team would appreciate your involvement in that process but you need to bring up right issues with right people. The attached email shows you sharing your concern with Elena – who is just a call center rep. The concern you shared with her is very serious and I suggest you bring these to me real time like you have done in the past. However you should also know that every time you have brought such concerns, I have reacted and always addressed them. This is why it is important you escalate your concerns to people who can fix them – like Chinmany, Nishit or myself if you think they may not be receptive to your ideas.

7. I also noticed that in couple of your emails you cc:ed your gmail address. These emails contain HIPAA protected patient information that should not travel outside of secure email channels (ours is secure). Please delete the patient info from these at your convenience.

thanks.

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**From:** Christian Holmes  
**Sent:** Thursday, October 09, 2014 1:06 PM  
**To:** Maximillion Fosque  
**Cc:** Sunny Balwani  
**Subject:** FW: Please call Dr. Palmer

Sunny FYI

**From:** Amelia Aguirre  
**Sent:** Thursday, October 09, 2014 11:40 AM  
**To:** Christian Holmes  
**Subject:** Please call Dr. Palmer

Hi Christian,

Could you please call Dr. Alan Palmer on his cell phone @ 

Eric Nelsen from sales is the one who called to say that Dr. Palmer had not received a call back and wants someone to call him back today.

I'm not aware of all the details of what has been discussed, maybe Adam can provide more info on that before you call him.

Thank you,

Amy

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**From:** Adam Rosendorff  
**Sent:** Thursday, October 09, 2014 11:32 AM  
**To:** Amelia Aguirre  
**Subject:** RE: Dr. Palmer

Please let Christian handle this-

I am unable to provide more insight regarding the discrepant results, and have not had any response from the ELISA group on this.

Thanks,

Adam

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**From:** Amelia Aguirre  
**Sent:** Thursday, October 09, 2014 11:29 AM  
**To:** Adam Rosendorff  
**Subject:** Dr. Palmer

Hi Adam,

Confidential

THPFM0000288404  
SEC-USAO-EPROD-000671294

Were you speaking with a Dr. A. Palmer regarding free & total testosterone? He said he was waiting for a call back about a patient [REDACTED]

DOB [REDACTED] but never got another call back.

He provided his cell phone # [REDACTED] if that's what is needed to return his call. He's hoping to get a call back today.

Please let me know if this was you working with him or if I should forward this to Christian.

Thank you,

Amy