To: Elizabeth Holmes[eholmes@theranos.com]; Sunny Balwani[sbalwani@theranos.com]
From: Daniel Young
Sent: Wed 2/26/2014 3:23:02 AM
Importance: Normal
Subject: RE: syphilis validation
Received: Wed 2/26/2014 3:23:04 AM

Correct.

From: Elizabeth Holmes
Sent: 2/25/2014 7:21 PM
To: Daniel Young; Sunny Balwani
Subject: RE: syphilis validation

And that the way they did it was wrong?

From: Daniel Young
Sent: Tuesday, February 25, 2014 7:12 PM
To: Elizabeth Holmes; Sunny Balwani
Subject: RE: syphilis validation

Yes, he was again happy to understand that there was a solid plan and process in place (other than what he understood beforehand).

From: Elizabeth Holmes
Sent: Tuesday, February 25, 2014 7:10 PM
To: Sunny Balwani
Cc: Daniel Young
Subject: Re: syphilis validation

Did he understand the PT point? Agree with the below.
On Feb 25, 2014, at 10:20 AM, "Sunny Balwani" <sbalwani@theranos.com> wrote:

> How long did you spend with him? This seems to be an overkill.
> On Feb 25, 2014, at 7:55 AM, "Daniel Young" <dyoung@theranos.com> wrote:
>
> > I had a follow-up discussion with Tyler yesterday. In summary:
> > - He acknowledged now understanding the calculations, so this issue is closed
> > - I reviewed our approach of meeting both CLIA and FDA requirements, and he was very impressed (and I should say he seemed somewhat relieved)
> > - He was happy to learn about FDA's very positive feedback and their enthusiasm for our technology and validation approach
> > - We did not review the 510k that he had found. Rather I explained to him that these studies are idealized studies that do not capture actual performance in a laboratory setting across laboratories. Our objective is to outperform other lab services providing these tests in national way by maintaining control and monitoring the entire process. He expressed understanding the power of this approach, such as the ability to trend results over time.
> > - Regarding performance claims, he seemed very surprised that I asked him where he thought we claimed superior performance over other tests. The best he could come up with was saying he thought that superior accuracy was mentioned in some of the articles that have been written about Theranos. I asked him to follow-up and highlight these specifically for me.
> > - The only surprising part of the conversation for me is that Tyler brought up PT (proficiency testing). He was aware of the recent data from CLIA where they tested PT samples both on Immulite and Theranos LDTs. (By the way, this goes against our CLIA SOPs as I noted in the other email, and indicates to meet a lack of understanding about how we validated our tests, limitations of PT, and how best to ensure performance of our LDTs moving forwards.) Tyler expressed concern about the apparent poor performance and was wondering how this was being dealt with (ie, were we reporting it, etc). I explained to him our PT policy as it stands now:
> > - PT for FDA cleared tests
> > - AAP to ensure our LDT accuracy against these predicates
> > - The main reasons for this policy being that there is no peer group for our LDTs

- All data are documented and available for audit review
- All results not meeting stated/documented acceptance criteria require immediate corrective action by CLIA

I was naturally disappointed to hear that these PT data were being discussed broadly, as it was the wrong thing to do with these PT samples, and it clearly can create miss-understandings.

Please let me know if you have any questions.

-Daniel

From: Sunny Balwani
Sent: Friday, February 21, 2014 9:15 AM
To: Daniel Young
Cc: Elizabeth Holmes
Subject: RE: syphilis validation

We are better in trending, our platform is better and in the LT even our assays are better since we are submitting everything to FDA. but at this point we are not making any claims around individual assays so ask him where he sees we are making claims around syphulus or other assays.

On calculations: you have explained enough. If he comes back to you, you can re-explain but the point should be what we are doing is high bar and this is what FDA is used to seeing and this is what we have submitted and submitting to FDA and that should be end of it. you don't have to be his math tutor and you should say it such.

Thanks.

From: Daniel Young
Sent: Friday, February 21, 2014 8:05 AM
To: Sunny Balwani
Cc: Elizabeth Holmes
Subject: RE: syphilis validation

I don't think that we make such a claim. Not that I have seen on the website at least.

From: Sunny Balwani
Sent: Friday, February 21, 2014 7:50 AM
To: Daniel Young
Cc: Elizabeth Holmes
Subject: Re: syphilis validation

Where are we claiming that our tests are better across the board?
On Feb 20, 2014, at 11:05 PM, "Daniel Young" <dyoung@theranos.com> wrote:

I met with Tyler regarding his questions about our ELISA validations and wanted to update you. He had two high-level questions/concerns:

- How were the calculations performed for the validation reports?
- Is the performance of our assays truly better than predicates methods?

I explained our calculation methods and he was slow to understand. I am going to follow-up again with him, as he does not understand the reasoning behind running replicates. Namely, running replicates reduces the overall variance by taking the mean or median of the replicate values – for some reason he does not understand this. He sent me tonight his variance numbers again without averaging across the replicates.

Regarding his second question, Tyler was very interested in understanding if our tests (syphilis in this case) are better than predicate tests. I explained to him the performance of tests can be compared in a variety of ways, including precision, accuracy, limits of quantification, dynamic range, predictive value, sample size requirements, etc. He expressed concern that we are claiming that our tests are better than other available tests, and he expressed doubts in the

case of our syphilis test. After we met, Tyler found a 510k approved test that he thinks may have better performance than our test. I am reviewing how we compare to this predicate and then meet with him again.

-Daniel

From: Elizabeth Holmes
Sent: Friday, February 07, 2014 10:33 AM
To: Daniel Young; Sunny Balwani
Subject: RE: syphilis validation

Your fast turnaround on this was appreciated -

From: Daniel Young
Sent: Thursday, February 06, 2014 10:22 PM
To: Elizabeth Holmes; Sunny Balwani
Subject: syphilis validation

I reviewed the validation report and the supporting raw data as summarized below. Highlighted in green text below are perfect matches. The orange highlights note some difference between the raw data/Excel files and the Validation Report, but as I have noted below, the differences are not a major concern or a clear explanation is known. Please let me know if you have any questions or want me to talk with Tyler.

- Table 1: Dilution linearity: data matches
- Table 2: Calibration 1 Data: data matches
- Table 3: Cutoff 1 Determination: data matches
- Table 4: Calibration 2 data: they have mistakenly duplicated 2 replicates run; seems like a copy paste error; these "extra" data were not used in the subsequent calculations in the next table which was used to summarize the results of the calibration, so in effect, this mistake made no impact on the study result
- Table 5: Cutoff 2 Determination: data matches
- Table 6: Precision Contingency: sensitivity and specificity in validation report do not match Elisa Team excel file because Comp Bio calculated the results correctly excluding outliers. The results in the validation report are what Comp Bio (Aaron in this case) computed.
- Table 7: Precision data: raw data matches
- Table 8: Clinical Correlation: raw data matches
- Table 9, 10, 11: Predictive Values, Clinical Corr, Sens/Spec Summaries: data matches
- Table 12: Venous v. Fingerstick: raw data matches
- Table 13: Venous v. Fingerstick Comparison Summary: raw data matches
- Table 14: EDTA Plasma: raw data matches
- Table 15: Li Heparin Plasma: raw data matches
- Table 16: Serum: raw data matches
- Table 17: EDTA v. Li Heparin v. Serum: raw data matches
- Table 18: Interference: raw data matches
- Table 19: Cross-reactive samples: raw data matches
- Table 20: Analyte Stability Summary: raw data matches
- Figure 4: reagent stability plot: I haven't located the raw data for this yet. Likely stored somewhere else since it may be ongoing further stability results.

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