

To: Sunny Balwani[sbalwani@theranos.com]
From: Adam Rosendorff
Sent: Fri 11/8/2013 8:25:48 PM
Importance: Normal
Subject: RE: 300 U ave
Received: Fri 11/8/2013 8:25:50 PM

Sunny

This is very exciting that we are broadening our testing to a wider base!

There are a few issues that need to be addressed:]

Operational

- 1) CLSes need to control the information flow to LIS, CLSes need to have the ability in Normandy to suppress results, cancel orders, check pending logs, before the results are uploaded into Theranos LIS- There needs to be an absolute iron gate within CLIA where only CLSes or myself decide what can be released, and what tests are ready for release both in general (ie is this test valid) and in each particular case.
- 2) An internal dry run of CHem 18 plus 1 or 2 immunoassays, involving 30-50 patients each day (Saturday/Sunday) would help to identify areas of improvement- if we could do that over this weekend that would be ideal, however we would still need 5 days after that to analyze and optimize the process.
- 3) Reflex or repeat testing: where possible we should be able to keep leftover sample to do repeat testing (eg criticals) or reflex testing- do we have a robust barcoding system in place where we can go back and identify patients based on barcodes/SCUs?

Medical/Scientific

- 1) As communicated in previous emails, the sensitivity of Vitamin D, TSH and possibly cTNI assays is *not* where we want it to be. While these tests are adequate for screening purposes, to identify abnormal in the general population, they are problematic. The Vitamin D assay cannot differentiate deficiency (10- 25 ng/mL) from insufficiency (<10 ng/mL). The TSH assay has a lower limit of detection of 0.1-0.2 mIU/L which makes it a Second Generation TSH assay, whereas the norm today are Third Generation assays with sensitivities down to 0.004 units or less. The lower limit of detection of cTNI assay needs to be raised from .1 ng/mL to 0.1-0.2 ng/mL., because blank samples are giving the same measurements (in terms of signal and concentration) as samples with a nominal concentration of 0.1 ng/mL. I am concerned that these analytic challenges are being glossed over. These concerns have been communicated repeatedly to Daniel and Sharada.

Best regards,
Adam

From: Sunny Balwani
Sent: Thursday, November 07, 2013 8:14 PM
To: Adam Rosendorff
Subject: 300 U ave

Adam.

We would like to open our 300 university ave. store to public this coming Monday. We feel confident that we can handle ~30 samples/day from this location at this point. And it has been 2 months since we have been out in WAG. Its time to go live.

We will also be opening our first phoenix location next mid-week.

The key is to have perfect discipline and SOPs in place to make sure we have a plan for everything and everyone in the chain knows what needs to be done. We will work on this from now thru next 5 days and I know we will get this done.

I would like to ask at this time if you have a reason to think we need more time or test out something that we haven't thought about. We will be picking up samples every hour or so during November from the 300 university Ave location so I think at a point we will never have too many samples to deal with at one point.

Please let me know your thoughts

Thanks.