Message

From: Daniel Young [/O=THERANOS ORGANIZATION/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=DYOUNG]
Sent: 10/22/2013 5:48:18 AM
To: Elizabeth Holmes [eholmes@theranos.com]; Sunny Balwani [sbalwani@theranos.com]
Subject: RE: CLIA updates

Basically, there have been results for which all ISE results are out of range. For example, K is high, and Cl and Na are low relative to the reference range.

I'd like us to perform some more in-house studies just focused on these three ISE assays until we have this completely under control. Ideally, starting on Wednesday, we perform 2 BCD and 1 venous draw per subject. If we can do this in the morning and afternoon for 3 days, that would provide some good data.

From: Elizabeth Holmes
Sent: Monday, October 21, 2013 10:44 PM
To: Daniel Young; Sunny Balwani
Subject: RE: CLIA updates

What are the issues?

From: Daniel Young
Sent: Monday, October 21, 2013 10:42 PM
To: Sunny Balwani; Elizabeth Holmes
Subject: RE: CLIA updates

Just a quick update, we still are having ISE challenges. There are several results recently that are out of range normal that I do not believe. So as a result we are not reporting these results.

I asked Nick last week to perform some additional experiments as noted in the email below, and hope to have his update tomorrow.

Also, over the weekend, I discovered that the ISE wash lines on the Advia need regular maintenance. Evidently, the GC chemists did not know this. I am going to review with Sarah, and make sure that this is happening per our utilization rate and not leave it up to the GC chemists for these regular maintenance procedures.

-Daniel

From: Daniel Young
Sent: Thursday, October 17, 2013 10:07 PM

To: Sunny Balwani (sbalwani@theranos.com); Elizabeth Holmes (eholmes@theranos.com)
Subject: CLIA updates

I wanted to send a few updates related to CLIA operations to make sure you are updated:

1. We met with Adam/Kerry/Hoda today to review what new SOPs are needed

a. While many SOPs have been created for the new processes/assays, there is still more to capture in formal documentation

b. We reviewed at a high level what is needed for future inspections and areas typically probed by inspectors

i. As mentioned before, I would still like to do a mock inspection – perhaps in 2 weeks

c. I asked them to create a list of all SOPs that are still needed. We will review this list and then assign resources/timelines

d. We discussed that with the addition of new software automation/apps, some SOPs will be changed/updated

i. They strongly felt that we need to first document current practices to cover all testing that has been completed to date without software automation/apps

ii. Then we will update SOPs to cover changes associated with the new software automation/apps

e. We discussed QC needs for the new Theranos LDTs. I suggested the following strategy:

i. We will run daily device QC on all EDISON 3.5 devices being used for CLIA testing; we will define new metrics (based on Levey-Jennings/Westgard principles) to capture device performance over time (note that currently daily QC is not being run on these devices; a QC run takes 45 min, so I'd like to have someone assigned to run this in the CLIA; we can automate the analysis/algorithm in the LIS)

ii. For ELISA tests being run each day in CLIA, I suggest that we run a QC on 3 cartridges from the current lot of cartridges being used; this QC will be run by loading a control sample onto 3 cartridges and run on EDISON 3.5 devices. Results need to be within a pre-defined range to pass. If they do not pass, calibration must be renewed for this lot of cartridges. (Note that ongoing stability is being run on many of these assays.)

2. Proficiency testing:

a. I have not discussed proficiency testing yet with CLIA for LDTs

b. Please let me know if I should do so, as it will require some coordination/planning and documentation of these procedures

c. The general strategy I still recommend is to perform standard PT for all assays with FDA approved tests on clunkers; we will perform alternative PT testing for all our LDTs by comparing performance of our LDTs to to the predicate devices/assays. Once this approach is finalized, we need to document the process/criteria for each assay.

3. Electrolytes/ISE:

a. Our Na, K, Cl test results are still not as reliable as I would like.

b. I've asked Nick Haase to run some additional tests to see if we can use calibrators instead of controls on each plate to improve performance

c. I asked them to complete the experiments by end of Friday, so we will have a suggestion on any process improvements soon

4. ELISA tests:

a. There are several ELISA tests that have completed validation. However, as I noted previously, the performance of some of these can and should be improved. I don't want to lose sight of this, especially for the most common tests. We may want to assign a few ELISA chemists to these assays to explore refinements so we can improve our limits of detection and precision to meet performance of predicate platforms/assays.

Please let me know if you have any questions/suggestions.

Thanks,

Daniel Young, PhD

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