To: Sunny Balwani[sbalwani@theranos.com]
Cc: Elizabeth Holmes[eholmes@theranos.com]
From: Daniel Young
Sent: Tue 11/5/2013 6:08:41 AM
Importance: Normal
Subject: RE: Advia in normandy
Received: Tue 11/5/2013 6:08:42 AM

Sure thing.

-----Original Message-----
From: Sunny Balwani
Sent: Monday, November 04, 2013 10:04 PM
To: Daniel Young
Cc: Elizabeth Holmes
Subject: FW: Advia in normandy

The Advia/GC scenario continues to be a mess and if Rose is calling the shots then that worries me even more.

Please ask sam to work with Sarah tomorrow and make all 3 advias to be identical for now. Including advia 2 where we don't need to be experimenting with Theranos assays for now but get all 3 to be working reasonable similar to each other for now.

-----Original Message-----
From: Rose Edmonds
Sent: Monday, November 4, 2013 7:48 AM
To: Nicholas Haase; Sunny Balwani; Paul Patel; Sarah Cabayan; Adam Rosendorff; Kerry Elenitoba-Johnson; Daniel Young; Tina Lin
Cc: Elizabeth Holmes
Subject: RE: Advia in normandy

Dear Sunny,

I am somewhat concerned with the feasibility of making this change so quickly. Today we were going to start an experiment to try to help troubleshoot the ISE variability but it involves running samples on the same ADVIA 1 to 2 times a day for the next 3 days. We were going to use ADVIA 1 but the current plan may make that a problem (if ADVIA 1 gets assigned to only running CLIA micro-samples). We are also trying to complete some validation work on acetaminophen and maybe TIBC and LDH in the next day or two. The sooner we know which machines get assigned to which tasks, the better for us.

I agree with Nick that from our perspective ADVIA 1 is the best one for samples (both CLIA standard macro samples and new CLIA micro samples) and ADVIA 3 is best for R & D.

Since ADVIA 1 is the only one approved for Theranos T-CUP ISE testing, it is definitely the best candidate for running clinical samples. It also has the protocols for many of the immunoassays. If I were to choose an ADVIA for running the micro-samples, ADVIA 1 would be it. However, as I mentioned, it is also the best machine for the CLIA team's regular macro scale external samples from doctors so if the machine had to be only micro or macro, that would be an issue. Right now only ADVIA 1 is connected to the Labdaq and LIS system that CLIA needs for patient information transfer (not 100% clear on the details so sorry if I misspoke or misspelled). If it's okay for both micro and macro samples to be run on that machine then there's no problem. We probably have to transfer a few protocols off of here for R & D as well.

ADVIA 3 is the likely second choice as p-protocol sample testing machine. ADVIA 3 could probably accommodate the immunoassays in terms of reagents but as far as I know, someone would have to take the substantial amount of time needed to transfer all the protocols for the immunoassay protocols. Also, we would need the engineers to confirm that they can fix the ISE

dead volume issue and they would have to do that ASAP.

ADVIA 2 had immunoassay protocols but I'm not sure if they are still there and that was a saline ADVIA when those protocols were written so it would likely need to go back to saline or the immunoassay protocols would have to be altered to use a special diluent source. There are no p-protocols on that machine. ADVIA 2 seems the least suited to anything other than maybe immunoassay after someone converts it to saline or adjusts the protocols to draw saline from a special source.

-----Original Message-----
From: Nicholas Haase
Sent: Sunday, November 03, 2013 9:31 PM
To: Sunny Balwani; Paul Patel; Rose Edmonds; Sarah Cabayan; Adam Rosendorff; Kerry Elenitoba-Johnson; Daniel Young; Tina Lin
Cc: Elizabeth Holmes
Subject: RE: Advia in normandy

Sunny,

This is the current state of all three ADVIA's:

ADVIA 1: Upstairs in the CLIA lab, it is what we currently use to analyze Walgreens and Demo samples. It is saline-washed. Sarah and Kerry (and possibly Rose) can likely speak best on immunoassays, but a number of them may be on ADVIA 1. It has reagents for the Next 15, but, again, is mainly used for CMB and Lipid panel testing of samples.

ADVIA 2: In Normandy. Water-washed and used by Team 2 for integration/validation of Theranos chemistries.

ADVIA 3: In Normandy. Saline-washed and contains Siemens reagents and p-protocols. It is mainly used for validation of p-protocols (Next 15). Currently set up for all GC assays, minus the ISE assays. We are working with engineering to optimize T-cup dead volume so that the ISE assays can be properly executed on this instrument. After that is complete we can run the CMB and Lipid panels (and the Next 15 assays).

I believe we have enough open reagent slots to accommodate immunoassays on ADVIA 3. This would only use a single ADVIA and alleviate the need to switch back and forth between R&D and clinical samples on an instrument.

From GC Team 1's perspective (not taking software into account), ADVIA 1 is the instrument best able to analyze public samples, and ADVIA 3 is best for R&D purposes. However, I know ADVIA 3 has been used for software development, so let me know how we can best ease this transition.

Regards,

Nick

From: Sunny Balwani
Sent: Sunday, November 03, 2013 11:43 AM
To: Paul Patel; Nicholas Haase; Rose Edmonds; Sarah Cabayan; Adam Rosendorff; Kerry

Elenitoba-Johnson; Daniel Young; Tina Lin
Cc: Elizabeth Holmes
Subject: Advia in normandy

I would like the 2 Advias on Normandy to be 100% dedicated to CLIA micro samples starting this week (or next weekend at the latest). I would like 1 Advia setup to process ONLY our fingerstick/micro samples for GC and the other setup for our immunoassays. If we can consolidate this on 1 machine then that's great, but if we cant then we need to move R&D out of Normandy by end of the week or create controlled shifts for production vs R&D and calibrate machines accordingly.

I know this creates a problem for us potentially because we need 2 Advias for R&D – one with saline and one with water – so we will meet on this issue separately on Tuesday. But I would like Normandy to be ready for primetime this week by Tuesday.

All the software for the Lab is coming together reasonable well and will continue to get better over next 2 weeks, but I want to begin processing about 100 samples per day in CLIA coming from WAG and our PSC this week. We want to open up the WAG store to public by end of the week.

We will walk thru the CLIA team in detail on training etc by end of the week and also plan on how many people we need at a given time, how to batch the samples etc etc.

Please let me know if anyone has any concerns on this or advias.

CLIA team needs to make sure we have all the regants and supplies needed for Advias and other devices to process upto 200-500 samples at a given point from point of view of readiness.

Thanks.