To: Adam Rosendorff[arosendorff@theranos.com]
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Subject: transition report
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transition_MWP_05_2014.docx

Attached,

A transition report.

Hope this helps.

Mark

5/29/30

M.W. Pandori

Transition Index:

- **A.** HIV/HCV Smaller volume project
- **B.** EMC/Bugs
- **C.** Daily CLIA Admin Issues
- **D.** Other notes

A. HIV / HCV Smaller Volume Project

A validation study was designed and has begun to be executed. Steve Morin and Lina Castro presently own it, and have the study design which I provided to them. Brian Martin has been aiding in the running of that study.

The project aims to utilize 70 ul of plasma, generated from CTN combined with 130 ul of lysis buffer to create a volume of 200 which we know the M2000 can work with during nucleic acid extraction. Initial data (possessed by Steve Morin and Lina Castro) indicated an approximate sensitivity of 500 copies per ml. In different experiments, approximately 20% of the tests failed for a variety of extraction errors. It is hypothesized that these extraction errors were due to having to perform a certain trick which involved pausing the M2000sp instrument in the middle of extraction. On 5/29, the Abbott technician was able to unlock the M2000sp so that Lina Castro and Tina Lin could put the proper program in place which abrogates the need for pausing.

50 specimens from San Francisco Dept. of Public Health with a range of viral loads of HIV-1 have been the basis for method comparison and validation. There continues to be high volumes of such specimens available.

Once the HIV project generates consistent data of reasonable sensitivity (500 is a reasonable threshold), it is thought that HCV could be validated by the same model. Both are RNA viruses that use similar or identical extraction reagents and protocols.

B. EMC/Bugs

Specimen Processing (room 201): Two biosafety cabinets are in place, along with lab benches. Certain SOP are being constructed or are finalized for the handling of urine, swabs, sputum, blood and culture fluid. Steve Morin is the owner of the SOP process. Centrifuges (2 clinical style) for the handling of blood and sputum are on order and on the way.

Culture: The culture room at EMC (Room 117) is fitted with a biosafety cabinet (already in place at EMC) and a fume hood. A refurbished Bactec 9240 is on order to arrive there the week of 6/16. There is a 2 day installation procedure followed by a 5 day validation procedure. Lina Castro possesses the validation instructions from BD. The Bactec 9240 allows for blood cultures to be performed however our chief aim is to use it to grow organism for 6-8 hours to boost the numbers into the sensitivity range of TNAA. This validation and SOP construction was being performed by Pranav's group, with some initial assist by Lina Castro and Steve Morin for SOP construction. What has not been validated is if blood is collected into containers other than the BD Blood culture vials and is subsequently transferred. It is

recommended that vacutainers used for that protocol contain no preservative that might harm the organisms present in the blood.

The BD Phoenix Device Array is not yet moved to EMC, but a req to pay BD to move this was created and approved this week. The Phoenix allows for positive cultures to be identified and for their drug susceptibilities to be determined. This is slated to go in the same Culture Room (117) at EMC along with the Bactec and two additional CO2 incubators which can be moved simply by truck from the culture room at 1601. With the biosafety cabinet, the Bactec, and the Phoenix, the lab should be ready on approximately 6/23 to be able to perform identifications of cultures from a wide variety of sources, including blood, in addition to performing drug susceptibility testing. The validation of the Phoenix for ID and for susceptibility testing is complete and as of last week was being written up by Ashkon Niroomand.

Culture-TNAA:

Cultured specimens from blood would be grown for 6-8 hours, transferred to pre-processing and placed into 96-well plates (in the same manner as swab fluids, sputums, and urines). 96 well plates are transferred to MSM-1 units in the adjacent room (room 109) in the workflow. Extraction on MSM units results in 96-well plates that are moved into the next adjacent room (room 113) in the workflow which contains the Hamilton. The reactions mixes are generated on the Hamilton and kept on chillers but are rapidly moved (at first by human beings) to the LightCyclers (room 301 due to power requirements). Initial drafts of SOP for these processes are owned by Steve Morin.

MSM-1 units are in place, and are functional (have been tested) at EMC. The Hamilton is in place and is functional at EMC.

LightCyclers are in place at EMC, but as of 5/23, their functionality there has not been established. The power requirements were initially an issue but was resolved by moving the units to a room where Matt Hernan could resolve that (room 301).

M2000: initially we had considered moving the M2000 to EMC. However the success of Pranav's GC/CT test and the fact that the majority of tests that require the M2000 are coming in to "CLIA", it makes more sense to leave the M2000 at 1601 until the move to Newark. Moreover, Abbott will charge 10,000 dollars to move the machine, or else it voids the service contract, so moving it twice seems disadvantageous.

Cold Storage: 4 deli style refrigerators are either in place or on order, in addition to 3 -20 freezers (in place), and a cold room. Racks for the cold room are at EMC. There is a -80C freezer at 1601 which is perfect for Bugs Lab for storage of positive samples. This will fill up but I anticipated ordering additional -80 in September when volumes increase and the lab is in Newark. The primary plan was to use the cold room for culture materials and antibody testing reagents. The -20s are destined to be used for storage of TNAA reaction materials.

Personnel: Four staff members dedicated to Bugs Lab hired to date: Steve Morin (technical supervisor), Lina Castro (CLS, Safety Officer), Ashkon Niroomand (CLS), Brian Martin (Lab Tech). They understand the equipment and the process very well, as they have been involved in building EMC and learning the Hamilton and MSM-1 units. They have authored or are authoring the validations and SOP for Bugs Lab processes.

C. CLIA Admin, daily issues that require or have achieved transition:

1. **Chiefly used for safety and HIPPA training is our subscription to MediaLabinc.net.** I have transferred primary administrator privileges to Adam Rosendorff. I have made Lina Castro, as safety officer, a subadministrator so that she could assign safety courses to staff members as they start, and annually. It is imperative that all incoming staff immediately receive HIPPA training and that they pass the MediaLab-provided exam and keep their certificate onsite, all prior to initiating any contact with patient data. Additionally, I assign Chemical Hygiene, Bloodborne pathogen and fire safety to all incoming employees (all courses on MediaLab site are OSHA approved).
2. **Approving purchases (requires transition)**
3. **Reviewing timecards, fixing clock-in/clock-out errors (this happens with high frequency)**
4. **Approving Time Off request:**
    a. I am approving all time off requests of less than three consecutive days before I leave. However there are several instances of longer requests which I aim to leave "open":
        i. Steve Morin, November 2014, 8 days
        ii. Ashkon Niroomand, August 2014, 14 days
        iii. David Ramos, August 2014, 6 days

D. Other notes:

Edisons: The primary concern in this section is the available number of devices. For FT4, VitD and TSH, at least a doubling of the number of units is necessary, in my opinion. This is one of the sections where more staff (lab techs) would benefit the most. I have been informed that the units require service with high frequency, so a continuous monitoring of this section is warranted. Romina, Aurelie and Ann Ho

are the primary operators, with Romina and Aurelie performing double-duty on CBC (Normandy). I had requested that Gurbir train on this to be the CLS "in charge" of this section, but when S. Howard left, he had to focus more time upstairs and on resulting and releasing and so this created some delays in his training. Jamie is well trained in this area, but remains (as of last week) working in research, with Chinmay.

Chemistry: The "cloning" project is in progress, with most of Advia 2 validation complete. Hoda had been using Melissa to accomplish this, but staffing shortages required that we pulled Melissa back to patient testing. Attention is required to finish this project (Advia 3 validations), but Hoda had lowered its priority in light of staffing issues. David Ramos is the CLS with the most training and expertise in the Advia devices. He has trained Dung Nguyen and Bona Apai in recent days, but only while I waited for a period of time to pass for their Normandy access so that they could become more involved in Accessioning.

CBC: Romina and Aurelie do this down in Normandy, along with Nereyda and Kim on a rotational basis. The transition back to original testing method and away from Fruitfly has been non-problematic. I had requested Maria Millare to train on this in Normandy, but she had not accomplished this as of last week. Part of the issue was that she had to spend a great deal of time reviewing and releasing results.