

Message

From: Mark Pandori [/O=Theranos Organization/OU=Exchange Administrative Group (FYDIBOHF23SPDLT)/CN=Recipients/CN=Mark Pandori16D]
Sent: 5/22/2014 2:41:56 PM
To: Sani Hadziahmetovic [shadziahmetovic@theranos.com]
Subject: RE: Edisons

Ok, Sani.

Thank you for your attention and work to get this going. Let me know how I can assist.

Mark

From: Sani Hadziahmetovic
Sent: 5/21/2014 10:00 PM
To: Mark Pandori
Cc: Chinmay Pangarkar; Nishit Doshi
Subject: RE: Edisons

Thanks Mark. This is helpful. I'm getting involved because I've been coordinating the effort for assembling devices in Newark and having them shipped to CLIA. Based on what you outline below + doubling for the new collection sites we need approximately:

Assuming 2hr runtime per protocol (generous I believe)...

80hrs runtime for TSH – 10 readers @ 8hrs/day

40hrs runtime for FT4 – 5 readers @ 8hrs/day

44hrs runtime for Vit D – 6 readers @ 8hrs/day

56hrs runtime across TST, FT3, TPSA – 7 readers @ 8 hrs/day

+20% buffer/downtime = 34 readers TOTAL. Please correct me if my logic is off anywhere.

As I mentioned earlier, we have shipped a total of 70 devices intended specifically for CLIA use so reader availability should not be a problem, even when we bring on more assays. The issue seems to be that we are not qualifying enough devices and that devices intended for CLIA are being used for other purposes. Below is a comprehensive list of all the readers that are intended for CLIA use. We should verify that these devices are in fact being used by CLIA.

Nishit, as we discussed today, we can first identify all the idle devices as our low hanging fruit.

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From: Mark Pandori
Sent: Wednesday, May 21, 2014 7:29 PM
To: Sani Hadziahmetovic
Subject: FW: Edisons

Here is the email I sent to chinmay yesterday.

From: Mark Pandori
Sent: 5/20/2014 6:47 PM
To: Chinmay Pangarkar; Adam Rosendorff; Nishit Doshi; Aurelie Souppe; Romina Riener; Hoda Alamdar
Subject: Edisons

Hi, Chinmay, Nishit,

There remains an issue in Normandy with the number of Edison readers available for patient testing. We will surely need more readers for the following reasons:

1. The number of Edison tests is already challenging the number we have
2. A new workflow process will require all vacutainers with Edison-capable tests to be aliquoted into CTN and tested on Edisons
3. More stores are opening this week (we cannot estimate how many more specimens will be coming in as a result).

Using the current vacutainer numbers, plus the number currently run per day on average, these are the conservative estimates of what we will be seeing in about 2 weeks (estimates do not contain additions due to newly opened collection sites in AZ):

TSH: a minimum of 20/day

FT4: 10/day

Vitamin D: 11/day

Total of: TST, FT3, TPSA: 14/day

My inventory of readers available now is:

FT4: 3

HCG: 3

tPSA: 3

TSH: 2

Vit D: 3

TST: 2

TT3: 2

TT4: 2

There are apparently 2 additional readers for TSH, however they have not been characterized properly for use.

For TSH alone, we have about 10 test-hours of demand, not counting both QC runs and any reruns that are necessary. Of course other tests are demanding the attention of the Technician, so things are not run perfectly end-to-end, and so the amount of work is pretty high.

CLIA lab aims to bring more people into this section to train. However in order to be effective, extra people will need more readers.

I'd like to discuss a plan to double the number of readers for the three main tests. This will be necessary as more stores will be opening in June, and we still don't know the impact of the openings in May.

I will propose a time to meet on this.

Thanks

Mark