

To: Elizabeth Holmes[eholmes@theranos.com]
From: Daniel Young
Sent: Tue 10/22/2013 8:57:27 PM
Importance: Normal
Subject: RE: Tests in CLIA lab
Received: Tue 10/22/2013 8:57:28 PM
Assay Testing Summary in CLIA Lab 10_22_2013 v3.xlsx

See updates attached. Thanks.

From: Elizabeth Holmes
Sent: Tuesday, October 22, 2013 1:48 PM
To: Daniel Young
Subject: RE: Tests in CLIA lab

yes

From: Daniel Young
Sent: Tuesday, October 22, 2013 1:47 PM
To: Elizabeth Holmes
Subject: RE: Tests in CLIA lab

Will this work:

Column title: "Chemistry and Protocol"

Tests that use Theranos chemistry and protocol: "Theranos"

Tests that use FDA approved chemistry and Theranos Protocol: "Theranos Protocol"

From: Daniel Young
Sent: Tuesday, October 22, 2013 1:10 PM
To: Elizabeth Holmes (eholmes@theranos.com)
Subject: RE: Tests in CLIA lab

Hi Elizabeth,

Please see the new second tab: "Plan to Do" in the attached document.

This now includes all tests that we have developed in house (or should by and of the year) or that are available in CLIA. There are a total of 384 tests included. Here is a summary of how I have marked the tests.

Cytometry:

- For CBC, I have listed all tests as Theranos Chemistry and TSPU for the device.
- For all urine based cyto assays, I have listed them as FDA approved (chemistry and device)
- T/B/NK assays I have listed as Theranos Chemistry and TSPU for the device.
- There are two manual tests that are available in CLIA that I have listed (Manual Differential; Ova & Parasites Smears)

General Chemistry:

- All GC blood tests that we are running on Advia I have listed as Theranos Chemistry and FDA approved device.
- All GC urine tests I have listed as FDA approved.
- For assays being run now on Tecan/M1000, I have listed as Theranos Chemistry and TPSU for the device.
- There are 22 tests for which the GC team developed an assay on the bench but the test is not available on Advia. I have listed these tests as Theranos Chemistry and TPSU for the device.

ELISA:

- if we developed the assay for blood on Edison devices, I have listed it as Theranos Chemistry and TSPU (even if we are running it on Advia right now).
- If the test is an urine test and available on FDA approved devices in CLIA, I listed them as FDA approved (no matter if we have an chemistry developed for this or not)

TNAA:

- On Abbott, we have the following 5 FDA approved TNAA tests: Chlamydia trachomatis, n.gonorrhoeae, hiv-1, hep C, heb B; I currently have them listed as FDA approved for both chemistry and device. Note that we are developing/validating all these 3 in-house, but that validation bar is very high for these.
- I've kept in the FDA approved Blood Culture Identification Panel (BCID) Panel as an FDA approved chem/device (it is from Biofire/Filmarray)
- All other TNAA tests that we are developing/validating (including those we have available from Biofire/Filmarray) I have listed as Theranos Chemistry and FDA approved device

Please let me know your feedback.

-Daniel

From: Daniel Young
Sent: Monday, October 21, 2013 7:57 PM
To: Elizabeth Holmes (eholmes@theranos.com)
Subject: RE: Tests in CLIA lab

How does this look for the "have done" tab?

Test	Chemistry	Device
CBC	Theranos	FDA approved
CMP	Theranos	FDA approved
Lipid	Theranos	FDA approved
Urinalysis	FDA approved	FDA approved
TSH	Theranos	TSPU
PSA	Theranos	TSPU
VitD	Theranos	TSPU
HbA1c	FDA approved	FDA approved
Uric Acid	FDA approved	FDA approved
DHEA-S	FDA approved	FDA approved
Total, Testosterone	FDA approved	FDA approved
Free, Testosterone	FDA approved	FDA approved

From: Daniel Young
Sent: Monday, October 21, 2013 7:37 PM
To: Elizabeth Holmes (eholmes@theranos.com)
Subject: Tests in CLIA lab

Hi Elizabeth,

Attached is a spreadsheet that lists all tests that have been performed on subjects since 9/9/2013.

I organized it for now as follows:

- Each subject order is on a row
- I've included order info, visit date, and reported date
- All tests run to date are listed on the first line (this includes a few tests that are not LDTs)
- For each subject, I listed what method was used for each test reported

Please let me know if you have any questions or if there is some information that is missing that you would like. Also any format changes that would be helpful.

I'll keep this updated, and we are working on making this a standard report we can create from the database.

-Daniel

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