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From: Daniel Young

Sent: Mon 8/19/2013 6:12:31 AM

Importance: Normal Subject: test launch list

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Launch Summary 8 18 2013.xlsx

The current launch list covers 200 tests, in both blood and urine samples. The collection of these reportables covers >97% of test frequency for these two matrices. (Note that | have not yet included TNAA tests on this list.)

Blood tests for launch include GC, ELISA and Cytometry:

- A total of 158 tests/reportables
- 48 are color chemistry
 - o 3 on M1000/Tecan
 - o 4 on imaging station
 - o 30 on Advia with Theranos chemistry
 - o 11 on Advia with Siemens chemistry
- 92 are ELISA
 - o 62 on Edison
 - o 30 on Advia with Siemens chemistry
- 18 are cytometry

Urine tests for launch include GC, ELISA and Cytometry:

- A total of 47 (note that some of these are in both urine and blood)
- 25 on Iris
- 20 on Advia (with Siemens chemistry)
- 2 on Edison (ELISA)

I have attached this launch list for your review. Please let me know if you have comments before I send updates to the teams.

One major effort includes validating all 64 ELISA's on Edison devices. I am still reviewing their validation plan to see if it can be further accelerated. As I noted, including all Edison 3.0 devices (in addition to 3.5 devices) in this effort would help expedite the process. We also need to make a push to update/create all protocols based on the ELISA team's updates for moving to 3uL of sample. Having the entire ELISA team devoted to these efforts would be helpful.

Also, we have about 40 assays to verify on Advia with Siemens chemistry – this should be relatively fast since only verification is needed.

Note that urine tests on Iris and Advia do not require any validation/verification.

There are a few gaps in the top 98% for which initial launch is currently not planned, and I am following up on these with the project leaders as required. Here is my current understanding:

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- automated reticulocyte count: slated for next round
- albumin, urine: may need to include Theranos chemistry
- Ketones (beta-hydroxybutyrate): TBD
- troponin, quant (tCNI): launching with troponin T instead
- acid (d-lysergicacid diethylamide, LSD, LSD-25, lysergide): under development
- butorphanol (Stadol, Stadola): TBD
- flunitrazepam (Rohynphol, Rohipnola): TBD
- Codeine (opiate screen): TBD
- Ipecac :TBD
- Nalbuphine, Nubain: TBD
- lyme disease antibody: this is a confirmatory test, traditionally western blot
- inf a / inf b: this CPT requires visual observation
- fibrin degradation, quant: under development

Thanks,

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