

To: Mark Pandori[mpandori@theranos.com]
From: Sunny Balwani
Sent: Tue 2/25/2014 10:15:22 PM
Importance: Normal
Subject: RE: Parallel testing for VitD, TSH, PSA and FT4.
Received: Tue 2/25/2014 10:15:21 PM

I would like to do this for these 4 assays this week and additional assays at least once so we have the data and we can eliminate the doubt that the PT samples have created in some people's minds. But I would like this perfectly planned. You should include Suraj and Daniel and Sam so they make sure we have the right cartridges, right processes and right data (basically do it in Normandy Lab as there everything does run correctly) so we do this right.

Thanks.

From: Mark Pandori
Sent: Tuesday, February 25, 2014 1:52 PM
To: Sunny Balwani
Subject: RE: Parallel testing for VitD, TSH, PSA and FT4.

Thank you for this.

To clarify, shall I hold off on initiating the QC measure we discussed in your office yesterday?

I've already organized all the CTN and drawing requirements (EDTA CTN, EDTA vacutainer, serum vacutainer per patient) with InHouse Studies and BCD.

And I've discussed execution with a small intra-CLIA team, including Langly, whom I've put in charge.

The proper specimen types per method were going to be used and results compared.

Mark Pandori

From: Sunny Balwani
Sent: Tuesday, February 25, 2014 1:23 PM
To: Mark Pandori
Subject: FW: Parallel testing for VitD, TSH, PSA and FT4.

FYI.

From: Adam Rosendorff
Sent: Tuesday, February 25, 2014 1:23 PM
To: Sunny Balwani
Subject: RE: Parallel testing for VitD, TSH, PSA and FT4.

Agreed- that way we can run the appropriate tube type on Theranos vs Predicate assays.

From: Sunny Balwani
Sent: Tuesday, February 25, 2014 1:03 PM
To: Adam Rosendorff
Subject: RE: Parallel testing for VitD, TSH, PSA and FT4.

Adam. For most/many of the predicates, EDTA-Plasma is not available as an option. This is why doing this as a inhouse study as we

discussed yesterday on bi-weekly/monthly basis will be better.

From: Adam Rosendorff
Sent: Tuesday, February 25, 2014 11:59 AM
To: Sunny Balwani
Subject: RE: Parallel testing for VitD, TSH, PSA and FT4.

For all EDTA-plasma vacutainers, if there is enough sample left over (regardless of what was ordered) I think we might want to run on both methods.

Adam

From: Adam Rosendorff
Sent: Tuesday, February 25, 2014 11:57 AM
To: Sunny Balwani
Subject: RE: Parallel testing for VitD, TSH, PSA and FT4.

Correction:

From: Adam Rosendorff
Sent: Tuesday, February 25, 2014 11:56 AM
To: Sunny Balwani
Subject: RE: Parallel testing for VitD, TSH, PSA and FT4.

Sunny

For all Edison Assays, the anticoagulant is EDTA-plasma. For predicate assays we have the following:

Vitamin D:	Serum
tPSA:	Serum
free T4:	Serum
TSH:	Serum

So we should change the preferred tube type for these vacutainer (venous) assays to EDTA-Plasma then so the matrix is the same- that's a good idea- Can I talk to Max about it?

Adam

From: Sunny Balwani
Sent: Tuesday, February 25, 2014 11:48 AM
To: Adam Rosendorff
Subject: RE: Parallel testing for VitD, TSH, PSA and FT4.

Please ensure that the method and sample collection for vacutainer samples in PSC for other instruments is compatible with what is needed for Edisons, i.e., same anti-coags, sample prep etc. otherwise this wont be accurate comparison. (I think this may be the case but given the confusions around PT, it is better to be explicitly make sure)

Also, I would suggest you only include members who are running ELISA assays and not the entire CLIA lab in this experiment and emails. The CLIA.LAB alias includes even the call center and super Mario team and I don't think they need to be involved with this. the following email doesn't explain to them why we are collecting this data (assuming the sample prep issues are non-issues) and this generates urban myths –especially people not involved with ELISAs or worse CLIA. during your next meeting with the team, it will be useful for you to walk them thru this and instill confidence in them that you and Mark know why we are doing this.

Thanks.

From: Adam Rosendorff
Sent: Monday, February 24, 2014 9:20 PM
To: Sunny Balwani
Subject: FW: Parallel testing for VitD, TSH, PSA and FT4.

Real time parallel testing:

Sent from my Windows Phone

From: [Adam Rosendorff](#)
Sent: 2/24/2014 4:36 PM
To: [CLIA.Lab](#)
Subject: Parallel testing for VitD, TSH, PSA and FT4.

All

When we get a venous tube only from WAG that requires a venous only test (such as LH) and also requires a test for VitD, TSH, PSA, or FT4, in addition to running an EDISON test for the latter 4 assays (current practice is to aliquot into CTNs and run as if they were FS samples), we should also run testing on predicate instruments parallel as follows:

- (1) Vitamin D- Diasorin
- (2) TSH- Imulite
- (3) FT4- Imulite
- (4) tPSA- Imulite

Please give both the EDISON result and the predicate result to Langly to be included in the spreadsheet.

Thanks,
Adam