To: Adam Rosendorff[arosendorff@theranos.com]
From: Sunny Balwani
Sent: Wed 11/5/2014 1:16:47 AM
Importance: Normal
Subject: RE: Theranos tests
Received: Wed 11/5/2014 1:16:49 AM

Adam.

this is not the case. And when a device fails, we always take the right corrective action and make sure it doesn't impact the quality of results. in any case, this would be adifferent point that using/not using multiple methods. we can discuss these next week in person. more productive.

thanks for the email.

From: Adam Rosendorff
Sent: Tuesday, November 04, 2014 5:14 PM
To: Sunny Balwani
Subject: RE: Theranos tests

Finally (and there is objective data on this), the rate of QC failure is lower on predicate devices than it is on Edisons, as is the throughput of predicate devices.

From: Adam Rosendorff
Sent: Tuesday, November 04, 2014 5:11 PM
To: Sunny Balwani
Subject: RE: Theranos tests

Sunny

My reasoning is that in that case we would be measuring our analyte on serum obtained from venous blood, whereas all of our validations, as well as reference ranges, are designed to validate EDTA-plasma from capillary blood (including any bias corrections applied based on the sample coming from capillary vs venous). Secondly, the capillary blood collection process as well as the device itself impacts the reference range, which would not be captured simply by aliquotting venous blood into a CTN, or even bypassing the aliquotting process and running as the Edison LDT. Thirdly, if a patient is having an analyte tracked over time, the ULOQ and LLOQ will be different depending on whether we run the test on a predicate Siemens device versus an EDISON, and this is going to be confusing, and further, it is always best to use a single sample type and device if you are going to monitor patients results over time, because this takes any inherent discrepancy between venous and capillary as well as any differences relating to collection procedure, out of the equiation.

One test, one sample type, and a unique RR is the best and most transparent solution IMHO.

Adam

From: Sunny Balwani
Sent: Tuesday, November 04, 2014 5:01 PM
To: Adam Rosendorff
Subject: RE: Theranos tests

Adam.

I haven't spoken to Elizabeth yet but reading your email; why would we discontinue #2? our assays are able to process much smaller sample size and even when we collect in vacutainer our collections remain small and it does makes tremendous sense to run our LDT – for instance PSA, Vitamin D on Edisons or 4S or cyto. we don't think we should discontinue these.

We will touch base next week once we dig deeper into other points etc..

thanks.

From: Adam Rosendorff
Sent: Tuesday, November 04, 2014 4:12 PM
To: Elizabeth Holmes; Sunny Balwani
Subject: RE: Theranos tests

Sunny and Elizabeth

I have discussed this with the team (Swapna, Nishit, Daniel), and all that remains is to get your signoff.

Thanks,

Adam

From: Adam Rosendorff
Sent: Monday, November 03, 2014 10:10 AM
To: Elizabeth Holmes; Sunny Balwani
Subject: Theranos tests

Elizabeth and Sunny

I would prefer if all Theranos tests showed reference ranges that were specific to the sample type and method being used.

Eg.

(1) Capillary blood Theranos test

(2) Venous blood Theranos test

(3) Venous blood Predicate test

In terms of (1), we can easily establish the ranges for all tests based on patients already tested.

In terms of (2) we should discontinue this practice.

In terms of (3) we should use the manufacturer established reference ranges per the IFU.

Secondly, I would like the physician to be aware if a test was performed on fingerstick versus venous blood, and this should be made clear in the laboratory report. This would make the physician more understanding of discrepant results that might arise due to matrix/sample type effects.

Regards,

Adam