To: Mark Pandori[mpandori@theranos.com]; Sunny Balwani[sbalwani@theranos.com]; Adam Rosendorff[arosendorff@theranos.com]; Paul Patel[ppatel@theranos.com]
Cc: Elizabeth Holmes[eholmes@theranos.com]
From: Daniel Young
Sent: Sat 2/22/2014 4:40:13 AM
Importance: Normal
Subject: RE: Morning HDL Study Tecan Dilution Results
Received: Sat 2/22/2014 4:40:14 AM

Makes sense for now.

From: Mark Pandori
Sent: Friday, February 21, 2014 8:39 PM
To: Sunny Balwani; Daniel Young; Adam Rosendorff; Paul Patel
Cc: Elizabeth Holmes
Subject: RE: Morning HDL Study Tecan Dilution Results

Any patients pending or run on Advia three in the last twenty four hours could be rerun on Advia one, and resulted out.

This is my take on this.

Mark

From: Sunny Balwani
Sent:2/21/2014 8:26 PM
To: Mark Pandori; Daniel Young; Adam Rosendorff; Paul Patel
Cc: Elizabeth Holmes
Subject:RE: Morning HDL Study Tecan Dilution Results

Agreed.

From: Mark Pandori
Sent: Friday, February 21, 2014 8:20 PM
To: Daniel Young; Sunny Balwani; Adam Rosendorff; Paul Patel
Cc: Elizabeth Holmes
Subject: RE: Morning HDL Study Tecan Dilution Results

Daniel,

All of the predicate / venous specimens are run on Advia 1, while all p protocols are run on Advia 3. So the QC data you analyzed on Wednesday included Advia 1 and Advia 3.

My take, is that we could move p protocol specimens to Advia 1 and resume testing.
Monitor closely.

Meanwhile we troubleshoot the bias seen for the test, overall.

Mark

From: Daniel Young
Sent:2/21/2014 7:16 PM
To: Mark Pandori; Sunny Balwani; Adam Rosendorff; Paul Patel

Cc: Elizabeth Holmes
Subject:RE: Morning HDL Study Tecan Dilution Results

Note that Advia 3 was calibrated just recently, while Advia 1 was calibrated Jan 30.

I have not seen the QC data for Advia 1 –how does it compare to the consistently low QC data on Advia 3?

While Advia 3 is on average 10% to 15% lower than Advia 1 as I noted below, at this point cannot say which is more accurate.

Given the tight precision of the HDL and the total allowable error of 30% from CLIA/CMS, I do suggest that we can test and report HDL on Advia 1 or 3.

Other major conclusion is that the Fingerstick samples, pCTN, and our Theranos protocols are good.

Thanks,

Daniel

From: Mark Pandori
Sent: Friday, February 21, 2014 7:05 PM
To: Daniel Young; Sunny Balwani; Adam Rosendorff; Paul Patel
Subject: RE: Morning HDL Study Tecan Dilution Results

Daniel,

I was looking at the uncharted data with Paul earlier.

It seems possible to me, that the relatively low reads we have been seeing lately could be based upon:

1. the fact that we are running the p-protocol HDL on Advia 3. Had we run the p-HDL on Advia 1, some of the problem would go away.

2. both Advia 1 and Advia 3 have been reading consistently low for some other reason, according to the look back at the QC data that you provided on Wednesday

--So there could be two factors leading to the rather low values that we have been seeing occasionally (for specimens tested on Advia 3).

Note that given this data, all venous would look better than p-HDL, simply because all venous are always run on Advia 1, as is CLIA practice.

Anyhow, we need to decide what to do about patient testing, as the Lipid panel tests are piling up here.

Adam?

Mark

From: Daniel Young
Sent: Friday, February 21, 2014 6:37 PM
To: Mark Pandori
Subject: FW: Morning HDL Study Tecan Dilution Results

FYI:

From: Daniel Young
Sent: Friday, February 21, 2014 6:32 PM
To: Nicholas Haase; Adam Rosendorff; Paul Patel; Rose Edmonds; Xinwei Sam Gong; Curtis Schneider; Nishit Doshi
Subject: RE: Morning HDL Study Tecan Dilution Results

See plots in the attached. My summary is:

1) p-HDL on fingerstick and Venous are very comparable

2) p-HDL on fingerstick compares very well to predicate on Venous (better for Advia 3 than on Advia 1)

3) p-HDL and predicate method both on Venous show some differences at the high HDL concentrations, but are well correlated (performance is worse on Advia 1)

4) Advia 1 is reading 10% to 15% higher than Advia 3 for all sample types and HDL protocols

5) We do not see a problem of abnormally low HDL results

6) There was one low result for one replicate; this may have been a Tecan related issue since it affected all the lipid assays similarly; Nick is checking into this

Please let me know if you have any comments.

Thanks,

Daniel

From: Nicholas Haase
Sent: Friday, February 21, 2014 5:03 PM
To: Daniel Young; Adam Rosendorff; Paul Patel; Rose Edmonds; Xinwei Sam Gong; Curtis Schneider; Nishit Doshi
Subject: Morning HDL Study Tecan Dilution Results

Everyone,

Attached are the tabulated results from the Tecan-diluted Fingerstick and Venous samples from this morning's study, as well as the predicate venous results.

The key is as follows: P-xxxx = P-protocol; A3-1 = Advia 3 rep 1 (and so on).

The last three subjects were not fasting, hence the coloration of their patient numbers. Only one sample returned an HDL result below 35 mg/dL, and that one was low for all analytes. This is due to over-dilution, from either the Tecan picking up gel or hitting some plasma on the sidewall of the pCTN.

Let me know if anyone would like calculations and/or plots of anything in particular.

Overall, we did not see any low HDL samples, omitting the aforementioned exception. Advia 3 tends to report lower values than Advia 1, but there are different reagent lots on the instruments.

Let me know if anything else is needed. We are currently doing manual sample dilutions.

Regards,

Nick H.