

To: Adam Rosendorff[arosendorff@theranos.com]; Sunny Balwani[sbalwani@theranos.com]; Mark Pandori[mpandori@theranos.com]
From: Daniel Young
Sent: Wed 2/19/2014 9:47:12 PM
Importance: Normal
Subject: RE: Low HDLs
Received: Wed 2/19/2014 9:47:14 PM

Thanks. Just let me know when you have them and I can take a look.

From: Adam Rosendorff
Sent: Wednesday, February 19, 2014 1:39 PM
To: Daniel Young; Sunny Balwani; Mark Pandori
Subject: RE: Low HDLs

Daniel

I've asked David Ramos to pull all of the ADVIA p-protocol lipid values from the last 4 months- please let me know when you would like to review?

Thanks,

Adam

From: Daniel Young
Sent: Wednesday, February 19, 2014 1:24 PM
To: Sunny Balwani; Mark Pandori; Adam Rosendorff
Subject: RE: Low HDLs

Adam, in addition to Sunny's questions below, I'd also like to review the Oct-Dec 2013 QC that you were referring to. The QC data I've reviewed was from Jan 2, 2014 to yesterday.

Also, can you please pull all HDL lab results for the last four months? I'd like to see the distribution.

Thanks,

Daniel

From: Sunny Balwani
Sent: Wednesday, February 19, 2014 1:01 PM
To: Daniel Young
Cc: Mark Pandori; Adam Rosendorff
Subject: Re: Low HDLs

Specially if we have stored samples for these 5 patients, we she rerun them with new reagent.

Also, are these 5 consecutive samples that gave us low readings or were they random?

On Feb 20, 2014, at 2:20 AM, "Daniel Young" <dyoung@theranos.com> wrote:

Regarding Westgard rules – I think there is some confusion. There are actually two rules that I think our QC data failed:

Confidential

THPFM0000283860

- 10x rule: failure is defined as 10 consecutive observations on the same side of the mean line. This occurred for all 3 QC levels weeks ago.
- 4 1S rule: failure is defined as 4 consecutive observations on the same side of the 1SD line. Do have a defined SD for this assay that you were using to evaluate this rule?

I'm looking into other potential causes for low HDL values, but moving to new reagents and rerunning calibration for HDL on Advia seems like the first step that needs to happen in CLIA.

-Daniel

From: Mark Pandori
Sent: Wednesday, February 19, 2014 10:34 AM
To: Adam Rosendorff; Sunny Balwani
Cc: Daniel Young
Subject: RE: Low HDLs

Adam,

I recently discussed this QC data issue with Hoda, and I did assign this task of Advia QC acquisition to two CLA and Hoda in the course of my "Task Sheets" project.

Mark

From: Adam Rosendorff
Sent: Wednesday, February 19, 2014 10:17 AM
To: Sunny Balwani
Cc: Mark Pandori; Daniel Young
Subject: RE: Low HDLs

Sunny

Langly and I reviewed all the QC data for Oct-Dec 2013 for all the ADVIAs in early January. Looking at the Levey-Jennings QC for January and February so far, indeed we would have failed Westgard based on the 10 1s rule for level 1 at least, (10 consecutive QC runs below 1SD) . However, all of the QC is still acceptable for daily runs, and I do not think the consistently low control recovery for both Siemens and Therasnos methods, explains the extremely low patient values.

I have been asking the supervisors to collect the ADVIA QC data and present it to me monthly since our CLIA inspection. It seems this is not happening. I will impress upon them the importance of collecting monthly QC.

Thanks,

Adam

From: Sunny Balwani
Sent: Wednesday, February 19, 2014 7:57 AM
To: Adam Rosendorff
Cc: Mark Pandori; Daniel Young
Subject: FW: Low HDLs

Adam.

Please see below. This was my suspicion and I had team look into the raw data. This is also where we got dinged in the CLIA audit. This should have been caught during regular QC. Is anyone looking at QC for Advias?

From: Daniel Young
Sent: Wednesday, February 19, 2014 7:47 AM
To: Sunny Balwani
Cc: Elizabeth Holmes
Subject: RE: Low HDLs

Below is the summary. D-HDL is the Advia default protocol and P-HDL is the Theranos protocol (pre-diluted) run on Advia. The mean bias ranges from -13% to -16%, with little variance. There is little difference between the two protocols. The QC data should have been flagged as I mentioned, for being consistently biased. We have a released SOP in CLIA that was not follows ("Westgard and Levey-Jennings Quality Control Doc # CL SOP-00023").

QC Data							Assigned			
		Mean	SD	CV	Min	Max	Avg	Min	Max	Mean Bias
D-HDL	Level 1	23.6	0.48	0.02	22.5	24.6	27	21.6	32.4	13%
P-HDL	Level 1	23.6	1.10	0.05	17.1	24.4	27	21.6	32.4	13%
D-HDL	Level 2	43.8	0.90	0.02	41.5	46	51.3	41.04	61.56	15%
P-HDL	Level 2	43.9	1.95	0.04	33.1	47.3	51.3	41.04	61.56	14%
D-HDL	Level 3	65.2	1.39	0.02	61.8	68.5	77.2	61.74	92.66	16%
P-HDL	Level 3	64.8	1.87	0.03	58.1	70.1	77.2	61.74	92.66	16%

-Daniel

From: Daniel Young
Sent: Tuesday, February 18, 2014 6:22 PM
To: Sunny Balwani
Cc: Elizabeth Holmes
Subject: RE: Low HDLs

At first glance, the HDL QC data looks to be running consistently low (very roughly 10% low). These QC data should have raised an alarm flag several weeks ago. The QC results seem similar for both the default Siemens protocol, as well as for the Theranos diluted protocol.

CLIA should have a person who is reviewing the QC data on a periodic basis. This deficiency came up in the last CLIA audit – I am not sure if they are doing this on a regular basis now or not.

-Daniel

On Feb 19, 2014, at 5:04 AM, "Adam Rosendorff" <arosendorff@theranos.com> wrote:

Daniel and Sunny

We have been getting a spate of low HDL values:

██████████ 28 mg/dL

██████████ 35 mg/dL 2/17/2014

██████████ 23.5 mg/dL 2/14/2014 → resulted and reported

██████████ 28.6 mg/dL 2/18/2014

██████████ 34.8 mg/dL 2/17/2014

These are all around the 5th percentile or less- I suspect our HDL assay has failed and I do not want to report out this result until we fix it.

Thanks,

Adam Rosendorff, MD, FASCP

Laboratory Director

Theranos, Inc

(650) 856-4412 (Office)

(650) 823-4953 (Mobile)

(650) 852-9594 (Fax)

arosendorff@theranos.com