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|---|---|
| **From**: | Adam Rosendorff [/O=THERANOS ORGANIZATION/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=ADAM ROSENDORFD92] |
| **Sent**: | 2/21/2014 5:21:46 AM |
| **To**: | Sunny Balwani [sbalwani@theranos.com]; Daniel Young [dyoung@theranos.com] |
| **CC**: | Elizabeth Holmes [eholmes@theranos.com] |
| **Subject**: | RE: HDL values |

Sunny

To summarize (and sent in previous emails):

(1) Patient data and analysis, Dec, Jan and Feb--> Feb patient mean is 54 mg/dL versus 62 and 65 mg/dL for Dec and Jan respectively.
(2) Analysis of HDL QC data since 9/29- all  3 levels consistently below mean (~10%) for both p-protocol and predicate assay, however low HDLs only started happening mid February.
(2) Comparison of 5 persons HDL values (completed yesterday), venous- p-protocols and predicate.--> Data matched closely--> Thanks to Hoda for initiating this.
(3) Planned study for Tuesday involving FS and venous--> moved to tomorrow.

Thanks,

Adam

**From:** Sunny Balwani
**Sent:** Thursday, February 20, 2014 9:08 PM
**To:** Daniel Young; Adam Rosendorff
**Cc:** Elizabeth Holmes
**Subject:** RE: HDL values

Since we found this issue on Monday. Did we run demo/test samples in Normandy to trouble shoot the problem? What did we learn

**From:** Daniel Young
**Sent:** Thursday, February 20, 2014 9:05 PM
**To:** Sunny Balwani; Adam Rosendorff
**Cc:** Elizabeth Holmes
**Subject:** RE: HDL values

Understood.  We'll have the study results as soon as possible in the AM, and triage any issues as required.

-Daniel

**From:** Sunny Balwani
**Sent:** Thursday, February 20, 2014 8:55 PM
**To:** Daniel Young; Adam Rosendorff
**Cc:** Elizabeth Holmes
**Subject:** RE: HDL values
**Importance:** High


We must resolve this asap.


Daniel, put everyone needed on this project including sam and erez, nishit and tina. We cant not revert back to venipuncture for HDL.


**From:** Daniel Young
**Sent:** Thursday, February 20, 2014 8:00 PM
**To:** Adam Rosendorff; Sunny Balwani
**Cc:** Elizabeth Holmes
**Subject:** RE: HDL values


Yes, please have them prepare for the study for tomorrow morning.  Thanks.

-Daniel

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**From:** Adam Rosendorff
**Sent:** ý2/ý20/ý2014 7:27 PM
**To:** Daniel Young; Sunny Balwani
**Cc:** Elizabeth Holmes
**Subject:** RE: HDL values

It's only since mid-February that we have started to see markedly low HDL values (5th percentile or less).


**From:** Adam Rosendorff
**Sent:** Thursday, February 20, 2014 7:27 PM
**To:** Daniel Young; Sunny Balwani
**Cc:** Elizabeth Holmes
**Subject:** RE: HDL values


Daniel


Thanks- if we can do the study tomorrow that would be ideal- HDL, unlike Triglycerides and total Cholesterol, is not sensitive to fasting versus non-fasting. The sooner we can fix the problem the sooner we can revert to FS. Should I notify in-house studies to send out an announcement?

Do you think that a delay in sample processing of the CTNs might be exacerbating the problem?


Thanks,


Adam Rosendorff, MD, FASCP

Laboratory Director

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(650) 856-4412 (Office)

(650) 823-4953 (Mobile)

(650) 852-9594 (Fax)

**arosendorff@theranos.com**


**From:** Daniel Young
**Sent:** Thursday, February 20, 2014 7:09 PM
**To:** Adam Rosendorff; Sunny Balwani
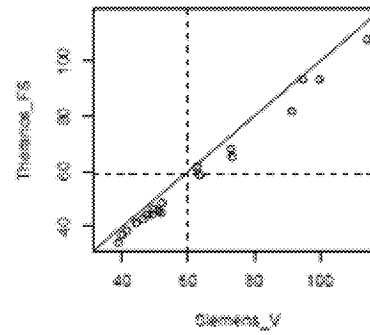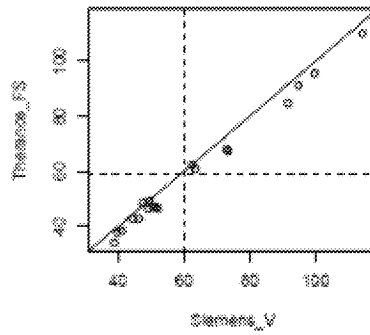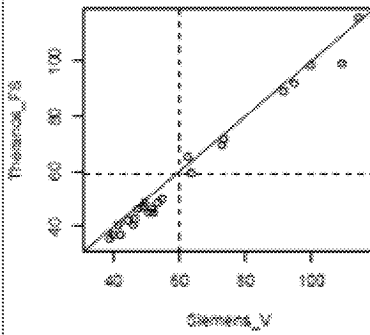**Cc:** Elizabeth Holmes
**Subject:** RE: HDL values


Adam, can we complete the mini-study tomorrow morning? Is this going to be using fasting samples?


I pulled some of the old data (see plots below) comparing the p-HDL protocol results from fingersticks/pCTN compared to the standard protocol using venous samples. There are 3 plots corresponding to sample storage in the nanotainers for 12, 24, and 36 hours. There looks to me at the low end of the HDL range a very slight under-recovery of HDL compared to venous results.

T12 P-HDL, x: 15/24, y: 15/24 = 62.50%    T24 P-HDL, x: 11/19, y: 11/19 = 57.89%    T36 P-HDL, x: 11/19, y: 12/19 = 63.16%

-Daniel


**From:** Adam Rosendorff
**Sent:** Thursday, February 20, 2014 6:21 PM
**To:** Sunny Balwani; Daniel Young
**Cc:** Elizabeth Holmes
**Subject:** HDL values


Hi Sunny and Daniel


I would like to discontinue p-HDL testing, and revert to LiHep vacutainer samples for HDL, until we have found out what the root cause is for the low HDL values, and corrected the problem. I do not feel that reporting this HDL in light of the spate of low HDLs we have been having, is good medical practice.


Today we had another low HDL value: HDL of 31.3 on CTN 55202, which we are currently repeating.


I have coordinated a split study for Tues to look at 15 subjects to compare venous with FS HDL- Venous will be run on predicate and FS with the p-protocol.


Thanks,


Adam Rosendorff, MD, FASCP

Laboratory Director

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