

To: Aurelie Souppe[asouppe@theranos.com]; Erika Cheung[echeung@theranos.com]; Jamie Liu[jliu@theranos.com]; Romina Riener[riener@theranos.com]; Nereyda Buenrostro[nbuenrostro@theranos.com]
From: Langly Gee
Sent: Fri 3/21/2014 12:32:03 AM
Subject: FW: Week 2 Vitamin D results

All:

Based on these emails, I am increasing the number of samples for Vitamin D testing to n=10 for next two weeks. All other assays will be done at n=5 (fT4 and TSH).

Langly

From: Sunny Balwani
Sent: Wednesday, March 19, 2014 7:20 PM
To: Mark Pandori; Langly Gee; Adam Rosendorff; Daniel Young
Cc: Hoda Alamdar; Suraj Saksena; Sharada Sivaraman
Subject: RE: Week 2 Vitamin D results

Absolutely, we have know this and both FDA and CLIA have mentioned this along with lab directors who said they usually have 40% variability in Vitamin D. UCSF had commented on this also.

From: Mark Pandori
Sent: Wednesday, March 19, 2014 7:08 PM
To: Sunny Balwani; Langly Gee; Adam Rosendorff; Daniel Young
Cc: Hoda Alamdar; Suraj Saksena; Sharada Sivaraman
Subject: RE: Week 2 Vitamin D results

Ok,

Langly, note.

Also, All,

Attached, is an interesting paper I've found on the topic of variability of Vitamin D assays on various methods/equipment. It may be useful in regards to our effort to establish fair ranges of acceptability for AAP this analyte, which seems notorious for variability on even FDA approved tests.

Mark

From: Sunny Balwani
Sent: Wednesday, March 19, 2014 7:01 PM
To: Mark Pandori; Langly Gee; Adam Rosendorff; Daniel Young
Cc: Hoda Alamdar; Suraj Saksena; Sharada Sivaraman
Subject: RE: Week 2 Vitamin D results

Agreed. Lets do this for vitamin D this way and others the way already planned.

From: Mark Pandori
Sent: Wednesday, March 19, 2014 6:59 PM
To: Sunny Balwani; Langly Gee; Adam Rosendorff; Daniel Young
Cc: Hoda Alamdar; Suraj Saksena; Sharada Sivaraman
Subject: RE: Week 2 Vitamin D results

I do like the idea of running on multiple devices.

Increasing the sample size to 10 or 20 and running on two devices is more difficult than it seems, for the reason that we plan to add TSH and FT4 to this study next Monday, and so that would mean either 60 or 120 runs on the Edisons; This would completely occupy the Edisons for one or two days, and I'm concerned that it will inhibit patient turnaround times. (Only one specimen can be run at one time on each Edison machine).

Mark

From: Sunny Balwani

Sent: Wednesday, March 19, 2014 6:28 PM

To: Langly Gee; Adam Rosendorff; Mark Pandori; Daniel Young

Cc: Hoda Alamdar; Suraj Saksena; Sharada Sivaraman

Subject: RE: Week 2 Vitamin D results

Only if they make sense. you guys can decide but seems like this will give us more data.

From: Langly Gee

Sent: Wednesday, March 19, 2014 6:26 PM

To: Sunny Balwani; Adam Rosendorff; Mark Pandori; Daniel Young

Cc: Hoda Alamdar; Suraj Saksena; Sharada Sivaraman

Subject: RE: Week 2 Vitamin D results

I will modify the study plan to accommodate your suggestions.

Langly

From: Sunny Balwani

Sent: Wednesday, March 19, 2014 6:24 PM

To: Langly Gee; Adam Rosendorff; Mark Pandori; Daniel Young

Cc: Hoda Alamdar; Suraj Saksena; Sharada Sivaraman

Subject: RE: Week 2 Vitamin D results

For next run, I would like to narrow down why 1 sample is off in this 5 runs.

Lets increase # of sample from 5 to 10 or 20 so sample size is more meaningful. 5 is too small.

Also, lets collect 2 fingersticks and run them on 2 devices as follows:

- Fingerstick 1 on device 1
- Fingerstick 1 on device 2
- Fingerstick 2 on device 1
- Fingerstick 2 on device 2

This will narrow down problem either with CTN or device if the recovery is too high. We need to solve this.

Thanks.

From: Langly Gee

Sent: Tuesday, March 18, 2014 1:26 PM

To: Sunny Balwani; Adam Rosendorff; Mark Pandori; Daniel Young

Cc: Hoda Alamdar; Suraj Saksena; Sharada Sivaraman

Subject: Week 2 Vitamin D results

All:

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See attached for week 2 Vitamin D results.

Langly