

To: Elizabeth Holmes[eholmes@theranos.com]; Daniel Young[dyoung@theranos.com]
Cc: Nishit Doshi[ndoshi@theranos.com]; Sunny Balwani[sbalwani@theranos.com]; Sharada Sivaraman[ssivaraman@theranos.com]; Ran Hu[rhu@theranos.com]; Samartha Anekal[sanekal@theranos.com]
From: Suraj Saksena
Sent: Sat 11/30/2013 7:31:44 PM
Importance: Normal
Subject: RE: Both QC Controls for Vitamin D didn't pass
Received: Sat 11/30/2013 7:31:45 PM

Hi Elizabeth

2 outliers had to be manually removed to pass QC. For future, we will incorporate automatic outlier detection and removal from analysis.

Thanks
Suraj

From: Elizabeth Holmes
Sent: Saturday, November 30, 2013 11:26 AM
To: Daniel Young
Cc: Nishit Doshi; Sunny Balwani; Sharada Sivaraman; Ran Hu; Samartha Anekal; Suraj Saksena
Subject: Re: Both QC Controls for Vitamin D didn't pass

What is the resolution.

On Nov 30, 2013, at 11:25 AM, "Daniel Young" <dyoung@theranos.com<mailto:dyoung@theranos.com>> wrote:

This has been resolved. Sample is being run on Edison.

From: Elizabeth Holmes
Sent: Saturday, November 30, 2013 11:24 AM
To: Nishit Doshi
Cc: Sunny Balwani; Daniel Young; Sharada Sivaraman; Ran Hu; Samartha Anekal; Suraj Saksena
Subject: Re: Both QC Controls for Vitamin D didn't pass

How fast can we resolve this issue.

On Nov 30, 2013, at 11:22 AM, "Nishit Doshi" <ndoshi@theranos.com<mailto:ndoshi@theranos.com>> wrote:
To the best of my knowledge, running Vit D on traditional method (Liaison) requires 150 ul of serum (not EDTA plasma). We cannot run this on Liaison since a dual EDTA CTN was collected for this patient to run Vit D on Edison.
Thanks,
Nishit

From: Elizabeth Holmes
Sent: Saturday, November 30, 2013 7:33 AM
To: Sunny Balwani
Cc: Daniel Young; Sharada Sivaraman; Ran Hu; Samartha Anekal; Nishit Doshi; Suraj Saksena
Subject: Re: Both QC Controls for Vitamin D didn't pass

Do we have enough sample to run this one on traditional methods?

On Nov 30, 2013, at 7:10 AM, "Sunny Balwani" <sbalwani@theranos.com<mailto:sbalwani@theranos.com>> wrote:
This is beyond unacceptable performance.

I will touch base with Suraj and others this morning.

On Nov 30, 2013, at 1:06 AM, "Erika Cheung" <echeung@theranos.com<mailto:echeung@theranos.com>> wrote:
Here's the data, each set of machine has its own tab and today's date labeled on it. Only one level passed for the set 3, everything else failed.

I'll have to clarify with Uyen on the details. She has been working on making the 2,000 cartridges for CAPSYS and has

encountered a lot of problems with various reagents in the process. Since she has been working closely with Suraj on this project, I assumed that this was something they tested and had problems with since he mentioned it. I'm not sure how long it will take to make new cartridges.

-Erika

From: Daniel Young
Sent: Saturday, November 30, 2013 12:49 AM
To: Erika Cheung; Normandy911
Cc: Sharada Sivaraman; Ran Hu; Samartha Anekal; Nishit Doshi; Suraj Saksena
Subject: RE: Both QC Controls for Vitamin D didn't pass

Thanks for the updates and efforts. Can you send out the data on your QC runs tonight?

What is the information supporting an problem with the pepsin for VitD? Also, how long will it take to make new cartridges with a new lot of pepsin?

-Daniel

From: Erika Cheung
Sent: Saturday, November 30, 2013 12:46 AM
To: Normandy911
Cc: Sharada Sivaraman; Ran Hu; Samartha Anekal; Nishit Doshi; Suraj Saksena
Subject: RE: Both QC Controls for Vitamin D didn't pass

Hi All,

I ran the QC controls on the second set of cartridges using a different bottle of substrate (within calibrated lot), and both QC controls failed.

We had two more sets of calibrated machines left (six machines in total), and I ran QC controls on both. I used all unopened reagents and a new package of cartridges for the last two sets, but these failed as well. I got into contact with Suraj, and he said it maybe the pepsin. It could also have something to do with this lot of substrate as well.

Uyen will be here tomorrow morning, I'll come in as well to help her troubleshoot what the problem is. I'll also be here on Sunday running patient samples, so I'll continue working on getting this fixed. If it's the pepsin tube, we'll have to make new cartridges. If it's one of the reagents, I'll have to recalibrate the machines and re-run the QC reference range which adds up to about 23 hours of work if things go smoothly.

If anyone has any suggestions, or if I missing something please let me know.

Best,

Erika

From: Erika Cheung
Sent: Friday, November 29, 2013 6:46 PM
To: Normandy911
Cc: Sharada Sivaraman; Ran Hu; Samartha Anekal; Nishit Doshi; Suraj Saksena; Suraj Saksena; CLIA.Lab
Subject: Both QC Controls for Vitamin D didn't pass

Hi Everyone,

I can't run Vitamin D for the Palo Alto received at 2:00pm today yet, both the QC controls didn't pass. The data is attached in the spreadsheet under the tab 11-29-13. It's possible it's a reader issue because there are abnormally high counts for machine E000351. I'm going to run QC controls on another set of machines to determine whether this is the issue or not.

If the QC controls pass on another set of machines, do I have permission to still run the patient sample?

Best,

Erika

<131114-Patient Samples_WAG_VitD_4Calibrations_MB.xlsm>