

Message

From: Mark Pandori [/O=THERANOS ORGANIZATION/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=MARK PANDORI16D]
Sent: 5/22/2014 4:35:17 PM
To: Max Fosque [mfosque@theranos.com]
Subject: RE: 33050 and 23321

No problem.

I wholeheartedly expected it all to play out exactly as it all played out.

Thanks, Max.

Mark

From: Max Fosque
Sent: Wednesday, May 21, 2014 6:50 PM
To: Mark Pandori
Subject: RE: 33050 and 23321

Thanks... should I not have sent that email, perhaps?

We would have looked very foolish in front of a large doctor's group if we had called one of those patients' for a 2nd redraw....

From: Mark Pandori
Sent: Wednesday, May 21, 2014 5:56 PM
To: Sunny Balwani; Max Fosque; Maria Millare; Adam Rosendorff; Daniel Young; Tina Lin; Nishit Doshi
Cc: Nicholas Menchel; Christian Holmes
Subject: RE: 33050 and 23321

I had been notified of this situation very recently, today, through Maria who was trying to review and release these.

The samples are both located and are scheduled to be run ASAP.

The Edison operators failed to enter these two specimens into the workflow. In a pursuit of why, it seems that at least

Part of the issue was that they were not using the pending lists now being generated each day, and instead relying on the binder downstairs with the specimen printouts. Tomorrow there is a CLIA wide meeting to discuss the utilization of the novel pending lists, and to review this issue.

Relatedly, I have on two occasions in the last 2 weeks requested more Edison readers to be made available in Normandy.

testing volumes are going up and having only 2 to 3 readers per test causes specimens to back up and for the workflow to

gain complexity. I am told that more readers are on their way, at least for the most common tests:

VitD, TSH, FT4.

Mark Pandori

From: Sunny Balwani

Sent: Wednesday, May 21, 2014 5:25 PM

To: Max Fosque; Maria Millare; Adam Rosendorff; CLS; Daniel Young; Romina Riener; Aurelie Souppe; Mark Pandori; Tina Lin; Nishit Doshi

Cc: Nicholas Menchel; Christian Holmes

Subject: RE: 33050 and 23321

cc:ing Mark, Tina and Nishit.

There are clear SOPs for where the samples need to be and where they are stored and should be stored. We cant be misplacing samples and calling patients multiple times for redraw. This is not only a bad idea but violation of SOP.

Mark and team will do a walkthrough to see where the samples are who was in charge of these so we can track them.

Thanks.

From: Max Fosque

Sent: Wednesday, May 21, 2014 5:13 PM

To: Maria Millare; Adam Rosendorff; CLS; Daniel Young; Romina Riener; Aurelie Souppe

Cc: Nicholas Menchel; Christian Holmes

Subject: RE: 33050 and 23321

Importance: High

CLS & CLA Teams,

Both Nanotainers were imaged on Friday, 5/16, at 5:33 PM. There was a CBC and Vit D ordered. CBC was run on Friday evening for both.

Stability on Vit D may be OK up to 1 week per Daniel Young.

Please find these samples. Since we store all samples for 1 week they should be in the lab somewhere. If not, please explain why so we can work to prevent this from happening in the future.

We cannot call these patients for a redraw unless absolutely necessary.

In parallel the LiHep from the previous visit for M-K is being sent to ARUP for VitD, per Gurbir's instruction.

Thanks,

Max

From: Anam Khan

Sent: Wednesday, May 21, 2014 3:42 PM

To: Maria Millare; Adam Rosendorff

Cc: CLS; Stacy Haff; Elena Scheer; Amelia Aguirre; Max Fosque

Subject: RE: 33050 and 23321

██████████ cannot be asked to be drawn again, she has already been redrawn once before.

Sent from my phone

From: Maria Millare

Sent: 5/21/2014 6:38 PM

To: Adam Rosendorff

Cc: CLS; Anam Khan; Stacy Haff; Elena Scheer; Amelia Aguirre

Subject: FW: 33050 and 23321

Adam,

There are 2 samples again that were missed. ██████████ for TSH and ██████████ for Vit.D. Redraw request has been submitted.

Thanks,

Maria

From: Romina Riener

Sent: Wednesday, May 21, 2014 3:12 PM

To: Maria Millare; Aurelie Soupe; Nafiseh Mirnezami; Ann Ho

Cc: CLS; Mark Pandori

Subject: RE: 33050 and 23321

Hi Maria,

Sorry for the delayed response, I've been searching through our written and online sources and I can't find any data for these samples. It seems that they were missed. We're trying our best to keep track of all of the samples.

Thanks,

Romina

From: Maria Millare

Sent: Wednesday, May 21, 2014 2:54 PM

To: Romina Riener; Aurelie Soupe; Nafiseh Mirnezami; Ann Ho

Cc: CLS; Mark Pandori

Subject: 33050 and 23321

Importance: High

Hello,

I sent an email yesterday about these 2 samples, didn't get a response. Have anyone tried to check what happened with 33050's TSH and 23321's Vit. D? I believe Hoda sent an email too.

Thanks,

Maria