

To: Sunny Balwani[sbalwani@theranos.com]
From: Elizabeth Holmes
Sent: Fri 4/25/2014 8:49:41 PM
Subject: RE: Dr. Kwatra/Dr. Stamps

FYI I am making sure this loop gets closed with Dr. Stamps. Please let me know if there are any other open WAG/patient/physician related issues you are aware of that I have not otherwise already referenced in my emails this afternoon.

From: Sunny Balwani
Sent: Thursday, April 17, 2014 3:39 PM
To: Elizabeth Holmes
Cc: Max Fosque
Subject: FW: Dr. Kwatra/Dr. Stamps
Importance: High

Ma ix going to come and talk to you about this issue. Adam and Daniel cant agree on this and he is in the middle of this. we need a right answer for this.

From: Adam Rosendorff
Sent: Thursday, April 17, 2014 1:20 PM
To: Sunny Balwani; Max Fosque; Daniel Young
Cc: Nicholas Menchel; Mark Pandori
Subject: RE: Dr. Kwatra/Dr. Stamps

Sunny

Including Mark here as well.

One further observation- *I do not believe that the levels of hemolysis that would result in a CTN K value >5.2mM are necessarily detectable by visual inspection by a CLS.* There is a hemolysis visual chart in CLIA that guides the CLSes in terms of what to accept and what to reject. CLSes have been instructed to reject a potassium result in the hemoglobin is >100mg/dL, which corresponds to calibrator level 6 on the hemolysis chart, however it is clear that we are seeing high potassiums in CTNs with lesser degrees of visually detectable hemolysis.

Adam

From: Adam Rosendorff
Sent: Thursday, April 17, 2014 1:08 PM
To: Sunny Balwani; Max Fosque; Daniel Young
Cc: Nicholas Menchel
Subject: RE: Dr. Kwatra/Dr. Stamps

Sunny

CTN potassium values are frequently above 5.2 mM, which is the upper end of the reference range. The upper end of the predicate range for venous plasma is 4.5mM for males and 4.4mM for females. I would guess that around 20% of CTN values are flagging as greater than 5.2mM.

I have instructed CLIA to report any potassium above 6.2mM as critical, to be in line with the standard of lab practice in the community. Previously our potassium critical was 7.6mM.

-Adam

From: Sunny Balwani
Sent: Thursday, April 17, 2014 12:43 PM
To: Max Fosque; Adam Rosendorff; Daniel Young
Cc: Nicholas Menchel
Subject: RE: Dr. Kwatra/Dr. Stamps

Max. can you please work with Daniel to get the images of this sample and see if there was any hemolysis (someone should have been following this process. This is part of our current SOP) and if so what actions were taken and how it was determined that the high K+ values should be released.

Thanks.

From: Max Fosque

Sent: Thursday, April 17, 2014 12:11 PM

To: Adam Rosendorff; Daniel Young

Cc: Sunny Balwani; Nicholas Menchel

Subject: FW: Dr. Kwatra/Dr. Stamps

Hi Adam & Daniel,

Please see the note below regarding a critical Potassium value.

Let me know if I can do anything to assist here.

Thanks,

Max

From: Kimberly Alfonso

Sent: Thursday, April 17, 2014 12:04 PM

To: Max Fosque

Subject: FW: Dr. Kwatra/Dr. Stamps

Hi there – please see below. How can we follow up here?

From: Mike Phebus

Sent: Wednesday, April 16, 2014 10:05 PM

To: Kimberly Alfonso

Cc: Mike Phebus

Subject: Dr. Kwatra/Dr. Stamps

Kimberly:

I am not sure who to send this email too in Palo Alto so I am forwarding to you. Here is some feedback from Kari Reedy in the field today:

Paradise Pediatrics - Dr. Kwatra / Dr. Stamps – (Pediatrics)

- Dr. Stamps likes our lab and has sent 3 patients. He does not trust our Potassium test, however.
1. He was called late at night regarding a patient that had abnormally high levels of Potassium. The patient was in NYC at the time of the call, so the doctor had to contact them while they were out of town. They did a re-test in NY and the results came back completely normal. Dr. Stamps said that K+ is a tricky one to collect because of clotting and such. He also mentioned that he is willing to share the specific patient information and explain the experience if someone wanted to reach out to him directly.
 2. Dr. Kwatra is kind of annoyed that we are unable to run tests on patients under 2 years of age. Working at a pediatric clinic, a lot of his patients fall into this category. I assured him that down the road there is a very good chance that we will be able to address those patients as well.

As you can see Dr. Stamps had a bad experience with one of his patients that he sent to us. Since this has to do with a lab test and results that did not seem to have the correct results I want to pass it on to the Product Management team for their review. Please forward to the appropriate Product Manager.

Have a GREAT DAY!

Mike Phebus

Theranos

