To: Elizabeth Holmes[eholmes@theranos.com]
From: Sunny Balwani
Sent: Sat 6/28/2014 9:50:35 PM
Importance: Normal
Subject: FW: Patient results since 5/24 for potassium
Received: Sat 6/28/2014 9:50:37 PM

From: Daniel Young
Sent: Saturday, June 28, 2014 2:39 PM
To: Sunny Balwani
Subject: Re: Patient results since 5/24 for potassium

Yes, our p-protocol on Advia and associated preprocessing steps and calibration scheme.
On Jun 28, 2014, at 2:35 PM, "Sunny Balwani" <sbalwani@theranos.com> wrote:

By our assay you mean our protocol. Right?

From: Daniel Young
Sent: Saturday, June 28, 2014 2:14 PM
To: Sunny Balwani; Adam Rosendorff
Subject: RE: Patient results since 5/24 for potassium

I wanted to provide a brief update on our review of potassium data and our refined focus to address this.

First, I was noticing that our potassium data from in-house samples has less issues than our WAG potassium samples. So we did some analysis and here is the summary:

Reported potassium results relative to our current reference range:

	% high	% normal	% low
WAG Phoenix	13	86	1
PA Phoenix	1	99	0
In-house	5	95	0

As this shows, samples from Phoenix are showing higher potassium results than WAG samples from Palo Alto and samples collected in-house.

I believe this is likely due to three combined effects:

1) sample storage time (longer storage on average for samples coming from Phoenix)
2) in-field and Normandy sample processing procedures (namely, centrifuge procedures) which may elevate potassium (likely dependent on storage time)
3) possible sample collection technique differences (impacting sample collection times), which may impact sample quality

We have planned a study to understand these factors and will then make refinements where needed. I think we are very close to having perfected our potassium assay, making it the most robust potassium assay from fingerstick samples in the world. In the new study, we are also reviewing how these factors can impact chloride, sodium, and others of our GC assays.

I'd like to complete these studies, update any SOPs accordingly, stabilize our process, and then evaluate the need to establish a new reference range for potassium if still needed. We have this reference range study plan finalized now, with Adam's input incorporated, so are ready to initiate if/when needed.

Thanks,
Daniel

From: Sunny Balwani
Sent: Wednesday, June 25, 2014 2:44 PM
To: Adam Rosendorff; Daniel Young
Subject: RE: Patient results since 5/24 for potassium

Adam.

I agree we need to resolve the Potassium issue. I am on the road thru Friday so will send out a meeting request for Monday. Thanks.

From: Adam Rosendorff
Sent: Wednesday, June 25, 2014 11:27 AM
To: Daniel Young
Cc: Sunny Balwani
Subject: Patient results since 5/24 for potassium

All

I wanted to give some summary statistics on performance of our potassium assay since it was optimized on 5/24.

Current reference range as validated and in LIS: 3.7-5.3 mEq/L

Total tests: 916
Void by lab: 57
Void by lab due to K critical high (>6.2mEq/L): 25
Void by lab due to K critical low (<2.8 mEq/L):5
Void by lab for reasons not listed: 27
Released with high flag: 94 (10.3%, expected 2.5%)
Released with low flag: 13 (1.4%, expected 2.5%)
Non-parametric RR excluding void by lab: 3.9-5.8 mEq/L
Non-parametric RR including void by lab: 3.7-6.0 mEq/L

Impressions:

- Too many potassiums are flagging high based on the RR we have chosen.
- Too few potassiums are flagging low based on the RR we have chosen.
- Our test is currently not capable of differentiating true critical potassium from potassium elevated due to collection, or, less likely, assay issues, because we are ordering redraw for all K>6.2 mEq/L.

I'd like to set up a meeting to review action items.

Thanks,

Adam Rosendorff, MD, FASCP
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