

Message

From: Nishit Doshi [/O=THERANOS ORGANIZATION/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=NISHIT DOSHI]
Sent: 10/27/2014 10:47:32 PM
To: Sunny Balwani [sbalwani@theranos.com]; Daniel Young [dyoung@theranos.com]; Tina Lin [tlin@theranos.com]
CC: Elizabeth Holmes [eholmes@theranos.com]
Subject: RE: Critical ISEs

Hi Sunny,

For ISEs, sometime results need to be voided if it is a process issue or sample integrity issue. We have asked CLIA to void the results in the following cases:

- 1) Sample integrity issues. This could involve interference, clots, bridge features etc
- 2) Short sampling on Advia
- 3) Dilution error in Tecan

ISEs are run after other assays ordered in CMP. So if there was enough sample to run other assays and if there was a dilution error or short sampling on Advia, then other assays will be released but not ISEs.

Thanks
Nishit

From: Sunny Balwani
Sent: Monday, October 27, 2014 3:40 PM
To: Daniel Young; Nishit Doshi; Tina Lin
Cc: Elizabeth Holmes
Subject: RE: Critical ISEs

I have not heard any issues on Advias or ISEs but I know there are issues that are now causing us a lot of pain.

Nishit/Tina. can I get an update on this? none of us are aware of these policy changes around so critical.

From: Daniel Young
Sent: Monday, October 27, 2014 3:37 PM
To: Sunny Balwani; Nishit Doshi
Cc: Elizabeth Holmes
Subject: RE: Critical ISEs

I have not heard about high frequency of critical ISEs. There have been some bring-up challenges of the Advia's and Nishit and team have been recalibrating to bring them in line. This was not specific to ISE's, however.

From: Sunny Balwani
Sent: Monday, October 27, 2014 3:26 PM
To: Daniel Young; Nishit Doshi
Cc: Elizabeth Holmes
Subject: FW: Critical ISEs
Importance: High

can I get an update on this? we are beginning to see all these issues and I am not getting this information from either of you or Tina. When I hear ISE issues from CLIA and not from anyone else, it makes us look bad. there is growing suspicion in CLIA that the non-CLIA team involved with CLIA lab tries to hide information from Elizabeth and myself and I

know that's not the case but we need to know about problems in real time so we can push on all fronts to solve the problem.

when did the following problem surface. I assume this is only on T Protocol and not on the predicate protocol.

From: Adam Rosendorff
Sent: Monday, October 27, 2014 3:20 PM
To: Sunny Balwani
Cc: Elizabeth Holmes
Subject: FW: Critical ISEs

Hi

I wanted to bring this important issue to your attention. Right now, after much cooperative discussion between CLIA and R&D and thought, if the CTN sodium is below 120mM or above 160mM we end up voiding the result, because we have no way of knowing for sure whether the result is truly abnormal or artifactual to the assay, or related to a specimen integrity issue.

Unfortunately, there are 2 conditions: Diabetes Insipidus and SIADH, where patients can live quite happily with a "Critical" sodium of <120mM or >160mM.

The patient below has diabetes insipidus which normally results in high sodium, but is probably being treated with DDAVP, which lowers the sodium. Therefore accurate measurement of sodium is important for this patient. I am not sure of the clinical value of a sodium assay, in which the only time we can report it is when it is *not critical*, and the very situations that require accurate measurement and reporting of abnormal of sodium results are voided. All of us in CLIA share the same concerns. How is the 4S Sodium doing? Maybe we can use the 4S for ISEs?

Thanks,

Adam

From: Anam Khan
Sent: Monday, October 27, 2014 3:08 PM
To: Adam Rosendorff
Subject: Critical ISEs

Hi Adam,

physician called today asking why ISEs weren't included on her final report. Only Comp was ordered, but ISEs were voided, so I explained that the patient would need to come back in to be redrawn. The lady I spoke to mentioned that they really needed the Sodium result because the patient had low Sodium levels and that's what they were checking. I noticed the Sodium results were critical low so I assume that's why we voided it. Is it possible that that was the true value? If she comes in again and the value is still critical low, will it just be voided again?

Thanks,
Anam