

## Message

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**From:** Sunny Balwani [/O=THERANOS ORGANIZATION/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=SBALWANI]  
**Sent:** 10/27/2014 10:28:14 PM  
**To:** Adam Rosendorff [/o=theranos organization/ou=exchange administrative group (fydibohf23spdlt)/cn=recipients/cn=adam rosendorfd92]  
**CC:** Elizabeth Holmes [/o=theranos organization/ou=first administrative group/cn=recipients/cn=eholmes]  
**Subject:** RE: Critical ISEs

no one briefed me on this so I am following up with Tina, Nishit, Daniel etc on this. will respond tomorrow.

**From:** Adam Rosendorff  
**Sent:** Monday, October 27, 2014 3:28 PM  
**To:** Sunny Balwani  
**Cc:** Elizabeth Holmes  
**Subject:** RE: Critical ISEs

We had a meeting with Tina, Nishit and the CLIA leadership about 6 weeks ago to come up with a consistent practice.

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

let me touch base with team on this one and will get back to you.

when did we start this policy?

**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