To: Daniel Young[dyoung@theranos.com]; Paul Patel[ppatel@theranos.com]; Samartha Anekal[sanekal@theranos.com]
Cc: Elizabeth Holmes[eholmes@theranos.com]
From: Sunny Balwani
Sent: Mon 3/31/2014 7:42:34 PM
Importance: High
Subject: FW: CO2 (Bicarbonate) issue
Received: Mon 3/31/2014 7:42:33 PM

Please drop by to discuss this.

Thanks.

From: Adam Rosendorff
Sent: Monday, March 31, 2014 12:38 PM
To: Sunny Balwani
Cc: Mark Pandori
Subject: CO2 (Bicarbonate) issue
Importance: High

Hi Sunny

At least 2/3 of our patients are reading below the normal range for bicarbonate (19-33 mM for CTNs). I do not expect outpatients to have abnormal bicarb values. Curtis's study with 6 days of data (24 data points) also shows that Bicarb is reading ~30% lower than matched venous, even after correction of the value for bias. The current best explanation is that there is rapid loss of CO2 from the CTNs during transport/processing. It is known that there is a loss of 6mM of bicarbonate for every hour a vacutainer is left open. Because of the small volumes we are dealing with, the rate of loss in our case is probably greater. ARUP specimen stability is 24hrs refrigerated. Our current validation report states that:

- Plasma samples for Bicarbonate analysis are stable sealed for 2 weeks at 2-8 °C.

However the ADVIA package insert says:

- Serum or lithium heparin plasma may be stored at 2-8°C for 7 days or at room temperature for up to 24 hours.

I wonder if Paul has any data on outgassing that we can use to decide on what our best course of action is.

CLSes have been asking me what we should do about Bicarb reporting. On the one hand, physicians are aware that if they want an accurate bicarb reading, they need to get the sample to the lab stat.

So far we have not had any phone calls regarding bicarb values- I think docs know that it's a highly context-dependant assay.

Your comments would be welcome.

Adam

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