

Message

From: Mark Pandori [/O=THERANOS ORGANIZATION/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=MARK PANDORI16D]
Sent: 2/11/2014 12:59:55 AM
To: Adam Rosendorff [/o=theranos organization/ou=exchange administrative group (fydibohf23spdlit)/cn=recipients/cn=adam rosendorfd92]
Subject: RE: QC for TSH Failed After Re-run

Thank you.

Mark

From: Adam Rosendorff
Sent: Monday, February 10, 2014 5:00 PM
To: Mark Pandori
Subject: RE: QC for TSH Failed After Re-run

Yes- it's ok if they do it- that is why we are running 3 EDISONS- to get enough data points and to average out variability.

Thanks,

Adam

From: Mark Pandori
Sent: Monday, February 10, 2014 4:59 PM
To: Adam Rosendorff
Subject: RE: QC for TSH Failed After Re-run

Ok,

So it is ok for the CLA to do this automatically until then. I assume.

Mark

From: Adam Rosendorff
Sent: Monday, February 10, 2014 4:55 PM
To: Mark Pandori
Subject: RE: QC for TSH Failed After Re-run

This rule will be part of the algorithm when the Edison 3.5 calculations are automated.

From: Mark Pandori
Sent: Monday, February 10, 2014 4:53 PM
To: Adam Rosendorff
Subject: FW: QC for TSH Failed After Re-run

Adam,

Is this something that the CLA can stand on as a policy, or do you want them to check with us first before doing this?

Thanks.

Mark

From: Adam Rosendorff
Sent: Monday, February 10, 2014 4:38 PM
To: Erika Cheung; Jamie Liu
Cc: Mark Pandori
Subject: RE: QC for TSH Failed After Re-run

Hi Erika

Yes we can delete as many as 2 of the 6 data points-

Adam

From: Erika Cheung
Sent: Monday, February 10, 2014 4:09 PM
To: Adam Rosendorff; Jamie Liu

Cc: Mark Pandori

Subject: RE: QC for TSH Failed After Re-run

Hi Adam,

Used a new BSA Buffer...still failed. If I delete to point that could possibly considered outliers on my rerun, the QC would pass. I attached the data showing what I am talking about. Otherwise, I'm not sure what to do now except wait until the CAPSYS QCs are completed.

Erika

From: Adam Rosendorff

Sent: Monday, February 10, 2014 2:46 PM

To: Erika Cheung; Jamie Liu

Cc: Mark Pandori

Subject: RE: QC for TSH Failed After Re-run

Its been colder the last day or two- is the instrument temperature correct?

From: Erika Cheung

Sent: Monday, February 10, 2014 2:42 PM

To: Adam Rosendorff; Jamie Liu

Cc: Mark Pandori

Subject: RE: QC for TSH Failed After Re-run

Everything was made recently either in late December or January. The earliest expiration date we have is 3/10/14.

From: Adam Rosendorff

Sent: Monday, February 10, 2014 2:40 PM

To: Erika Cheung; Jamie Liu

Cc: Mark Pandori

Subject: RE: QC for TSH Failed After Re-run

How old are the reagent cartridges?

From: Erika Cheung

Sent: Monday, February 10, 2014 2:38 PM

To: Adam Rosendorff; Jamie Liu

Cc: Mark Pandori

Subject: RE: QC for TSH Failed After Re-run

I tried that, it still fails.

Erika

From: Adam Rosendorff

Sent: Monday, February 10, 2014 2:36 PM

To: Erika Cheung; Jamie Liu

Cc: Mark Pandori

Subject: RE: QC for TSH Failed After Re-run

Please exclude the data point "1511" raw count from instrument E000187
and recalc.

Adam

From: Erika Cheung

Sent: Monday, February 10, 2014 2:19 PM

To: Adam Rosendorff; Jamie Liu

Cc: Mark Pandori

Subject: QC for TSH Failed After Re-run

Hi Adam,

I re-ran the level 1 QC for TSH, it failed again. The data is in the tab titled QC_2013.1.23-current under the row with today's date on it.

If we need to recalibrate, I'm just going to use the TSH CAPSYS cartridges. I should be finished running the daily QC information and getting the calibration finished by tomorrow or Wednesday. If this is the case, expect a delay on processing the patient sample until then.

Thanks,

Erika