

To: Adam Rosendorff[arosendorff@theranos.com]
From: Erika Cheung
Sent: Wed 2/5/2014 3:55:44 AM
Importance: Normal
Subject: RE: SOPs for EDISON Total T4, Total T3, Testosterone, FSH
Received: Wed 2/5/2014 3:55:46 AM

Hi Adam,

I talked to Mark and Suraj, they are just going to run the test on the FDA approved waived test and report the results from there. They told me there was no need to run the QCs, I can still run them if you need the data.

Erika

From: Adam Rosendorff
Sent: Tuesday, February 04, 2014 7:50 PM
To: Romina Riener; Suraj Saksena; Erika Cheung
Cc: Mark Pandori; Jamie Liu
Subject: RE: SOPs for EDISON Total T4, Total T3, Testosterone, FSH

Romina or Jamie please run the controls and let me know the results ASAP

Sent from my Windows Phone

From: [Romina Riener](#)
Sent: 2/4/2014 6:34 PM
To: [Suraj Saksena](#); [Adam Rosendorff](#); [Erika Cheung](#)
Cc: [Mark Pandori](#); [Jamie Liu](#)
Subject: RE: SOPs for EDISON Total T4, Total T3, Testosterone, FSH

Hi All,

I'll run the QC runs for the assay, but I don't feel comfortable running the patient sample. You're going to have to find someone else to do it. I'll let inform Jamie.

Erika

From: Suraj Saksena
Sent: Tuesday, February 04, 2014 6:29 PM
To: Adam Rosendorff; Romina Riener; Erika Cheung
Cc: Mark Pandori
Subject: RE: SOPs for EDISON Total T4, Total T3, Testosterone, FSH

Hi Adam,

There was a concern expressed to me regarding stability since we do not have stability data on the HCV capsys cartridges and they were made on 12/21/2013 (a little over a month). My suggestion was to run the C50, +50 and -50 and look at the data. If this QC fails, we will not run the patient sample. We will have to re-calibrate with fresh reagents (which I can provide).

I have handed off the C50, +50 and -50 samples to Erika to run and also told her which readers to use.

Thanks,

Suraj

Confidential

From: Adam Rosendorff
Sent: Tuesday, February 04, 2014 6:25 PM
To: Romina Riener; Erika Cheung
Cc: Mark Pandori; Suraj Saksena
Subject: RE: SOPs for EDISON Total T4, Total T3, Testosterone, FSH

Hi All

SOP and validation has been written, and approved. Interpretive comments should be in LIS.

Suraj is going to provide Capsys cartridges to us to run this test.

I think we should run the + and -50% cutoff controls that were run in the initial validation, AS WELL AS either the Zeptometrix controls or the Ortho HCV controls (negative, 1, 2 and 3), prior to running the patient sample.

Thanks,

Adam

From: Romina Riener
Sent: Tuesday, February 04, 2014 6:13 PM
To: Adam Rosendorff
Cc: Mark Pandori
Subject: RE: SOPs for EDISON Total T4, Total T3, Testosterone, FSH

This was the update we gave about the status of calibrating for all the assays. We don't write SOPs, all that is done by the ELISA team. We only calibrate and run daily QCs. Even though the SOPs become approved, that doesn't mean we have everything ready to start processing patient samples. I think this is the disconnect that occurred here.

-Erika

From:Erika Cheung
Sent: Tuesday, January 21, 2014 6:36 PM
To: Adam Rosendorff; Aurelie Souppe; Romina Riener; Jamie Liu
Subject: RE: SOPs for EDISON Total T4, Total T3, Testosterone, FSH

We've already been working on Total T4 (Aurelie), Total T3 (Romina) and total Testosterone (Erika). We are still working on gathering all the reagents for FSH. We are also working on getting the reagents for HCV (Jamie) at the moment as well.

Best,

Erika

From:Adam Rosendorff
Sent: Tuesday, January 21, 2014 6:34 PM
To: Aurelie Souppe; Romina Riener; Erika Cheung; Jamie Liu
Subject: SOPs for EDISON Total T4, Total T3, Testosterone, FSH

Can you folks please start working on these so we can implement these assays?

Maybe you can each tackle one?

Please use the existing Edison SOPs as templates:

J:\CLIA\CONTROLLED DOCUMENTS\VERSION5-REFERENCE ORIGINALS\09000-Technical Methods Chemistry and Immonoassay\EDISON 3.5 Immunoassay system

Thanks,

Adam Rosendorff, MD, FASCP

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