

Message

From: Surekha Gangakhedkar [/O=THERANOS ORGANIZATION/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=SUREKHAG]
Sent: 7/8/2013 4:26:14 PM
To: Emma Liu [eliu@theranos.com]; Salina Abusali [sabusali@theranos.com]; Tiffany Zhou [tzhou@theranos.com]; Esther Chan [echan@theranos.com]
CC: Ran Hu [rhu@theranos.com]; Tina Noyes [tnoyes@theranos.com]; Sharada Sivaraman [ssivaraman@theranos.com]; Karen Shaw [kshaw@theranos.com]; Ling Wang [lwang@theranos.com]
Subject: MTP assays

All,

As some of you know, we are going ahead with the CLIA/LDT validation of the following assays on the 384 plates. The assays and the assignments are shown below: Please coordinate and work in the guidance of the assay developers to ensure smooth transfers.

1. Vit D - Emma
2. Hb A1c – Emma
3. TSH - Salina
4. TPSA – Salina
5. Ferritin – Tiffany
6. Free T4 - Tiffany

The primary steps will involve Transfer and (any) optimization/fine tuning of the assays for the MTP, establishing a protocol for the Tecan liquid handler (that will run the tests), writing of the SOP and training and transfer to CLIA team.

This week let's get started on the checking the dose response and performance of the assays on the MTP. The point person for the Tecan will be confirmed soon.

Attached is the a draft of the CLIA-LDT validation plan for review. I will also forward the templates for the documentation.

Esther – Please ensure that 3 lots of Abs are available for these assays. We recently ordered new lots for Vitamin D.

Surekha