

To: Sunny Balwani[sbalwani@theranos.com]; Elizabeth Holmes (eholmes@theranos.com)[eholmes@theranos.com]
From: Daniel Young
Sent: Fri 11/15/2013 12:23:46 AM
Importance: Normal
Subject: RE: Assay Validation
Received: Fri 11/15/2013 12:23:00 AM

Quick summary of meeting with Sharada, Ran, Adam and Suraj:

- LLOQ:
 - I reviewed the FDA guidelines that were used for the ELISA assay development/validation (which are also part of Dexter)
 - We discussed the verification approach used by the ELISA team derived from CLSI guideline EP17
 - Adam said that he was ok with the results for troponin I (the validation report is now signed off)
- TSH:
 - We discussed the current LLOQ for TSH which is 0.1
 - Adam noted that some assays (3rd and 4th “generation” assays) on the market have lower LLOQ; note however that immulite’s LLOQ is higher
 - Adam wanted to add a note on the Lab Results indicating that our assay is “2nd generation”. I told him this was not what we are going to do, rather we just note that any value less than our LLOQ is noted as “<0.1”
 - We can work on lowering the LLOQ for this assay if we put more development time into it
- Vit D
 - We reviewed the latest data which nicely confirms the LLOQ of 10ng/mL
 - The already approved validation report is being updated to include these data

-Daniel

-----Original Appointment-----

From: Sunny Balwani

Sent: Wednesday, November 13, 2013 8:15 PM

To: Sunny Balwani; Daniel Young; Elizabeth Holmes; Sharada Sivaraman; Ran Hu; Suraj Saksena; Adam Rosendorff

Subject: Assay Validation

When: Thursday, November 14, 2013 1:00 PM-2:30 PM (UTC-08:00) Pacific Time (US & Canada).

Where: