

To: Elizabeth Holmes[eholmes@theranos.com]; Surekha Gangakhedkar[surekhag@theranos.com]; Ian Gibbons[gibbons@theranos.com]; Gary Frenzel[gfrenzel@theranos.com]
From: Susan DiGiaino
Sent: Wed 6/11/2008 2:00:15 PM
Subject: FW: Theranos Evaluation
Theranos Evaluation Summary 09 June 2008.doc

See attached summary of GSK's evaluation of our systems. I am following up with Rebecca Hodge as well as Derek and Bob Dobbins in regards to the upcoming AXOR study as well as additional opportunities.

From: nelson.n.rhodes@gsk.com [mailto:nelson.n.rhodes@gsk.com]
Sent: Wednesday, June 11, 2008 9:38 AM
To: derek.j.nunez@gsk.com; rebecca.j.hodge@gsk.com; robert.l.dobbins@gsk.com
Cc: Susan DiGiaino
Subject: Theranos Evaluation

Please find the attached Metabolic Biomarker Lab summary of the Theranos Systems evaluation that took place May 27-28, 2008.

Best regards,
Nelson

Background information:

On May 27-28, 2008 the Therasnos system was evaluated at GSK to profile active GLP-1 and C-peptide values and these data were compare to “gold standard” ELISAs using frozen human plasma from study AXO110461. The key project objectives (found in the attached statement of work) were:

[EMBED Word.Document.8 \s]

- To assess the performance of the Therasnos System in measuring GLP-1 and c-peptide values (the “Cartridge Analytes”) as compares to the current gold standard ELISA.
- To assess the functionality, specificity, reproducibility, accuracy, and precision of the Therasnos System.
- Assess the Therasnos data reporting and transfer functions

Thirty plasma samples (assayed in duplicate) were chosen based on historical GSK data for total GLP-1 levels from subjects given a mixed meal and two finger prick blood draws were performed. Five Therasnos machines were used with active GLP-1 and C-peptide cartridges that required 20µL of plasma. MesoScale Discovery’s (MSD) active and total GLP-1, Linco (Millipore) active GLP-1, and Linco (Millipore) C-peptide ELISAs were run as comparator assays.

Data:

Original data (attached):

[EMBED Excel.Sheet.8]

The original calibration for the Therasnos system was based on spikes into human blood and plasma and validated against the Linco ELISA kit. The baseline (background) signal for no spikes was higher than the RLUs seen for most of the samples in the GSK study.

Recalibrated data and correlations (attached):

[EMBED Excel.Sheet.8] [EMBED PowerPoint.Show.8]

GSK Metabolic Biomarker Lab comments:

- Data show good correlation
 - $r^2 = 0.90$ for GLP-1 (MSD vs. Theranos)
 - $r^2 = 0.96$ for C-peptide (Linco vs. Theranos)
 - inter-instrument precision acceptable (RLU average %CV = 11)
- Machines worked well
- Touch-screen interface was easy to use
- Cartridges were pretty straight forward (easy to handle and load)
- Assays took approximately 1 hour and 15 minutes per cartridge
- Finger prick/blood draw procedure was difficult (needed larger lancet and better syringe system)

Overall conclusions:

- The Theranos system eliminates the need for a lab and provided quality data
- The Metabolic Biomarker Lab has a favorable impression of the technology/system and recommends GSK clinical groups to work with Theranos to identify the best use of this technology.