To: Hobson, John (Peyton) [redacted] Hojvat, Sally A [redacted]
From: Elizabeth Holmes
Sent: Wed 10/16/2013 2:51:58 AM
Importance: Normal
Received: Wed 10/16/2013 2:51:00 AM
Theranos Workflow Diagrams_FDA_Confidential.pdf

Dear Peyton,

We've tried to compile comprehensive and simple workflow diagrams in follow up to our emails and as discussed on our last call.

Let me know if they make sense and if there are any questions or ambiguities and we can iterate them for you prior to circulation.

With my very best regards,

Elizabeth

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Overview of Sample Processing Workflow Prepared for FDA:

Phase I and Phase II of Theranos Business Operations

This presentation and its contents are Theranos proprietary and confidential.

Phase I: Current

Theranos PSC
(Theranos site operated by Theranos CLIA lab)

Clinician Test Order is Received

- Sample collection is performed in dedicated Theranos Patient Service Center
- Collection and processing performed by Theranos licensed phlebotomists/state-certified personnel trained and further certified by Theranos' CLIA lab
- Sample collected by venipuncture, finger stick, or urine collection
- Phlebotomist/state-certified personnel places sample in and operates centrifuge, performs relevant preparatory steps prior to sample transport (all industry standard procedures – n o ftheranos specific)

Theranos courier physically transports sample to lab for analysis

Theranos High-Complexity CLIA-Certified Lab in Palo Alto, CA

Samples are processed and results are generated via conventional analyzers

OR

Theranos Sample Processing Unit (TSPU) performs automated pre-analytic processing

TSPU transmits signals securely to TLAS for analysis

Theranos Laboratory Automation System (TLAS) performs automated analysis and post-analytic processing

TLAS provides control and oversight of TSPU

Data is sent back to ordering clinician from lab

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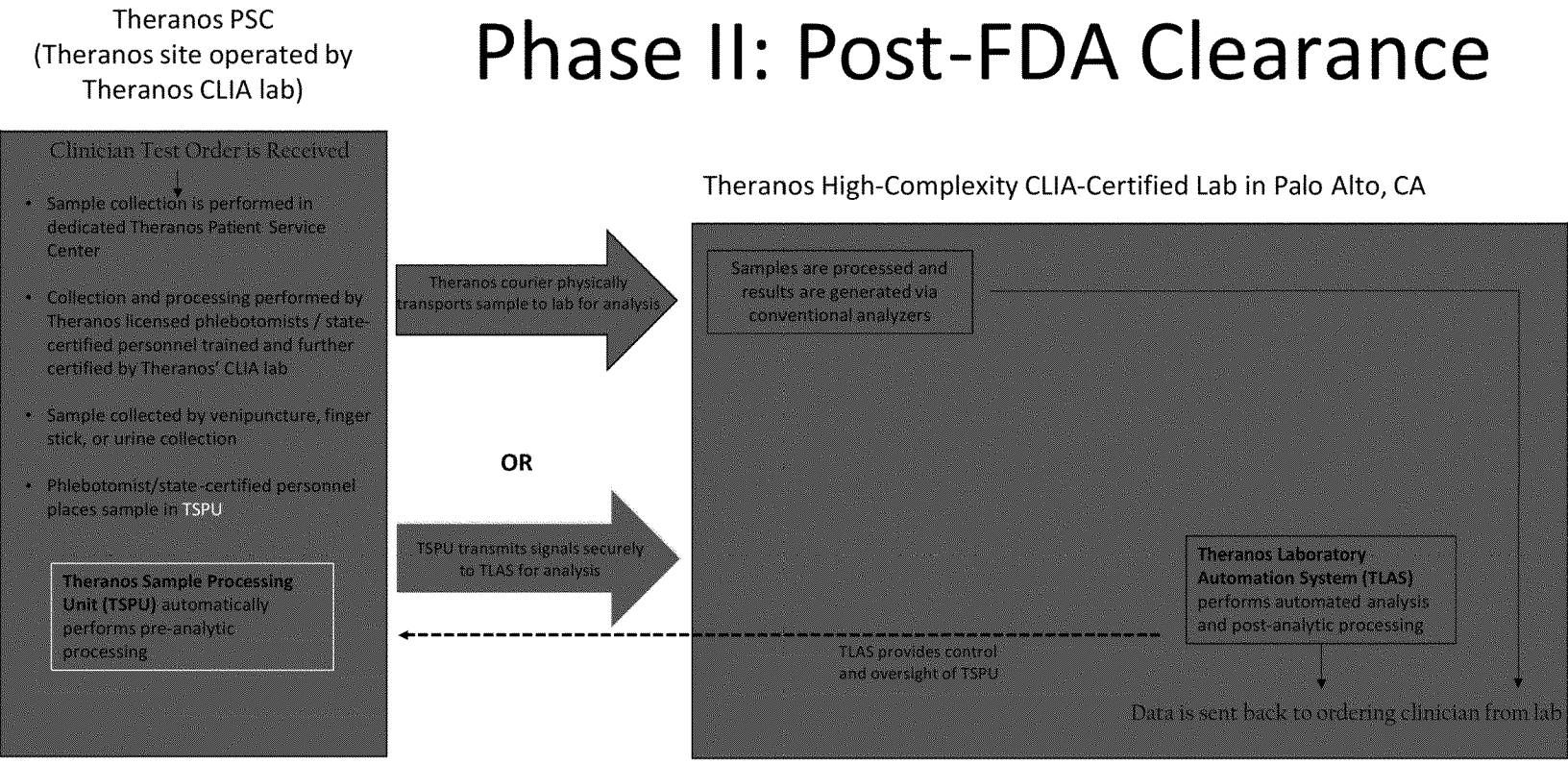
Phase II: Post-FDA Clearance



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TSPU & TLAS Description

(The TSPU and TLAS are designed and manufactured by Theranos with no third party involvement.
The TSPU and TLAS are also only used by Theranos and are not sold.)

Theranos Sample Processing Unit (TSPU)

Performs automated pre-analytic processing*:

- Sample separation (into plasma)
- Reagent addition/preparatory steps and associated signal generation
- Transmits raw signals (e.g. pixels or photon counts) to TLAS**
- Connected to and controlled by TLAS under the oversight of Theranos CLIA laboratory personnel

*No operator decision making or manual processing required
**NB – r e s u l t s cannot be generated on the TSPU (and thus of course could never be transmitted from or displayed on the TSPU)

Theranos Laboratory Automation System (TLAS)

Performs automated analysis and post-analytic processing:

- Pathologist and CLIA lab personnel oversight of TSPU
- Result derivation:
  - Signal analyzed
  - Replicates analyzed
  - Outliers analyzed
  - Controls analyzed
  - Calibrators analyzed
  - Signal converted to concentration based on analysis
- Pathologist and CLIA lab personnel oversight of analysis, post-analytic processing, and results