# theran<sub>os</sub>

# 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.

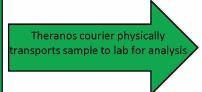
## Theranos PSC (Theranos site operated by Theranos CLIA lab)

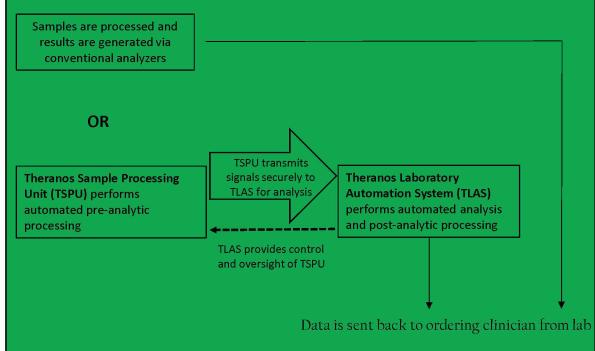
#### Clinician Test Order is Received

- Sample collection is performed in dedicated Theranos Patient Service Center
- Collection and processing performed by Theranos licensed phlebotomists/statecertified 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 – not Theranos specific)

## Phase I: Current

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





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## Theranos PSC (Theranos site operated by Theranos CLIA lab)

## Phase II: Post-FDA Clearance

#### Clinician Test Order is Received

- Sample collection is performed in dedicated Theranos Patient Service Center
- Collection and processing performed by Theranos licensed phlebotomists / statecertified 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 TSPU

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

Theranos High-Complexity CLIA-Certified Lab in Palo Alto, CA Samples are processed and Theranos courier physically results are generated via transports sample to lab for analysis conventional analyzers OR TSPU transmits signals securely Theranos Laboratory to TLAS for analysis 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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# **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 results 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

