theranos
redefining healthcare

Theranos, Inc. Confidential Information for AFRICOM Protocol

Background: Overview and Cost Savings.

Theranos is a high-complexity CLIA-certified laboratory headquartered in Palo Alto, California. Theranos manufactures proprietary clinical analyzers, assay reagents, and laboratory developed tests for the complete range of tests reimbursed by the Centers for Medicare and Medicaid Services.

Theranos tests are all validated with micro-liter sample volumes of the relevant biological matrices. For blood based assays, the assays are validated on micro-liter samples of serum, plasma, venous and finger-stick blood.

Part of Theranos' mission is to offer tests of unprecedented quality at unprecedented low costs. Costs per tests on Theranos systems are fractions of retail test or hospital test costs and in volume, very significantly discounted from US Medicare reimbursement thresholds. Theranos is working to offer laboratory services to Medicare and Medicaid programs in the US at rates far lower than current reimbursement thresholds to materially reduce federal and state healthcare spending.

Theranos manufactures all of its technologies and systems within the United States.

Design: Deployment.

Theranos' point-of-service laboratory infrastructure generates real-time data from a finger-stick of blood or other micro-volumes of different sample types delivering higher quality data than previously possible. This technology is an industry first, with profound effects on the ability to triage and stabilize patients via quantitative reads from micro sample sizes in real-time in the field.

Each Theranos device can process the complete range of tests currently available through the traditional centralized or hospital laboratory infrastructure. Theranos' device can process multiple samples on a given cartridge. Sample types include blood, urine, feces, tissue and saliva, amongst others. The cartridge can automatically perform follow-up tests when protocol dictates those additional tests are necessary.

For this program, the Theranos 3.0 system and accompanying cartridges will be deployable to designated sites in theatre. Devices can transmit data and video via satellite, short and long-wave radio, Ethernet, Wi-Fi, and cellular broadband to allow instant communication of test results to the necessary recipients.

The system is portable and designed to be able to be used at the point of sample acquisition. Theranos systems are highly automated with all pre-analytical, analytical, and post-analytical steps capable of being run by the system so that untrained operators can fully operate the system.

Embedded decision support on the device touchscreen allows for medical expertise to be provided to untrained operators in field.

Theranos Clinical Analyzers.

Theranos' clinical analyzers are capable of running the full spectrum of laboratory tests ranging from hematology to clinical chemistry, immunoassays, microscopy, and molecular based diagnostic tests.

The Theranos 3.0™ is a small, compact and portable analyzer that processes a single sample at one time.

Theranos clinical analyzers are capable of performing comprehensive pre-analytical and sample preparation procedures as well as analysis. In the context of placement of an analyzer in a Theranos CLIA laboratory, the device can automatically perform the pre-analytic and analytic procedures. The analyzers can also be used for sample preparation procedures only and transfer data remotely for analysis. Automation of many of the manual pre-analytic procedures contributes to acceleration of the total turnaround time of test results from the time of sample collection to analysis. Pre-analytic processing automation and integration also contributes to low coefficients of variation in system wide performance data.

Theranos clinical analyzers have integrated connectivity modes ranging from cellular connectivity to wired connectivity to radio for the purpose of transmitting comprehensive performance, quality, sample prep, and analytical information to a secure analytical infrastructure or into an EMR system.

Theranos clinical analyzers include touch screens with applications for clinical data entry. Test results are displayed as each assay is processed either on the touch screen and/or in an EMR as specified. The touch screen can also run training, support, and other applications to assist in ease of use and in data interpretation.

Theranos clinical analyzers are factory calibrated. Standardization of analyzers across Theranos locations has contributed to higher integrity data generation in past deployments. The ability to rapidly process fresh whole blood samples has further contributed to the integrity of Theranos test results.

Unlike waived devices, Theranos analyzers and the associated Theranos laboratory analytical software was designed to operate in a CLIA-certified laboratory framework with minimal human intervention. The level of integrated controls and oversight was introduced with the intent of operating in remote, scantily staffed, and/or rural environments.

Theranos Tests.

Theranos reagents are Analyte Specific Reagents. Theranos reagents are enclosed in the disposable reagent tray or cartridge into which the sample is deposited for analysis. While multiple reagents are contained in a single tray, all reactions are discrete. Reagent trays contain

reagents for a range of assay types. The largest number of assays run simultaneously on a single tray to date is 72. Reagent trays are customizable. Each reagent tray can process a finger-stick sample of blood to perform any given set of tests. Reagent trays are also customized for the full range of clinical sample matrices. The reagent tray is traced throughout its lifecycle through a unique bar code which is used for quality control purposes and monitoring reagent interactions.

Total test time of Theranos assays ranges from <1 minute for tests like PTT to <30 minutes depending on the analytes measured. Theranos has customized assay run times for prior deployments based on field requirements. Sample volume requirements range from <1 uL for a given assay to <50 uL for a given panel.

Theranos cartridges contain controls and calibrators for each assay. Assays are generally run in triplicates. All assays are validated under CLIA guidelines. Novel assays have been rapidly developed and validated on the Theranos platform for prior deployments. Representative data is attached.

Certifications, Quality Control, Safety and Related Infrastructure.

Theranos is a high complexity CLIA certified laboratory. Internationally, Theranos' model of operation is ISO certification of all CLIA laboratory facilities.

In all deployments, Theranos trains and certifies technicians operating in its sample collection sites and laboratory locations. Staff for Theranos laboratories can be assigned or contracted via existing (hospital) laboratory personnel. Theranos has been building a large distribution and support infrastructure which includes logistical hubs through which devices are replaced and serviced. Deployments always include additional back up devices for further modularity and redundancy; replaced devices are generally serviced offsite by Theranos personnel. As a CLIA lab, Theranos has not sold devices for deployments but rather provides a reference laboratory service. Theranos manages just in time inventory of reagent trays in its locations. Reagents are designed with minimum twelve month stability targets under the most robust conditions possible for a given assay. Theranos clinical analyzers are Class I medical devices classified under FDA 21 CFR Part 862.2160. In addition to its CLIA lab quality system standards, Theranos is QSR compliant.

While Theranos analyzers can be used for sample processing in the field, Theranos has also developed proprietary nanotainer™ (tiny vaccutainer that collects blood through a small capillary) which allow for micro volumes of sample to be stabilized in the appropriate anticoagulant and shipped to or processed in a clinical laboratory. Theranos nanotainer™s are classified as Capillary Blood Collection Tubes under 21 CFR Part 864.6150.

Theranos systems are Non-Invasive, Non-Significant Risk Devices. Theranos validates each assay under FDA and ICH Guidelines and where applicable, under/to WHO guidelines and standards.

Theranos is GLP and GMP compliant. Theranos software is validated under 21 CFR part 11. Theranos clinical analyzers are Class I medical devices classified under FDA 21 CFR Part 862.2160. In addition to its CLIA lab quality system standards, Theranos is QSR compliant.

All controls, calibrators, replicates, and QC testing mechanisms are automatically run with each test that is processed on board the system.

As a CLIA-certified laboratory, Theranos is legally liable for the accuracy of every result that it reports. This means that in addition to the controls, standards, and practices (such as Good Manufacturing Practices) required by FDA for Class I devices, Theranos devices are also subject to the ongoing testing, oversight, and regulatory obligations under CLIA certification.

Theranos is HIPAA and 21 CFT Part 11 compliant, utilizes bank-level encryption, and operates in compliance with a broad range of security standards and accreditation programs.

Theranos systems have undergone EMC testing, Underwriter's Laboratory (UL) certification, passed loose cargo vibration and drop/shock tests and extensive environmental testing.