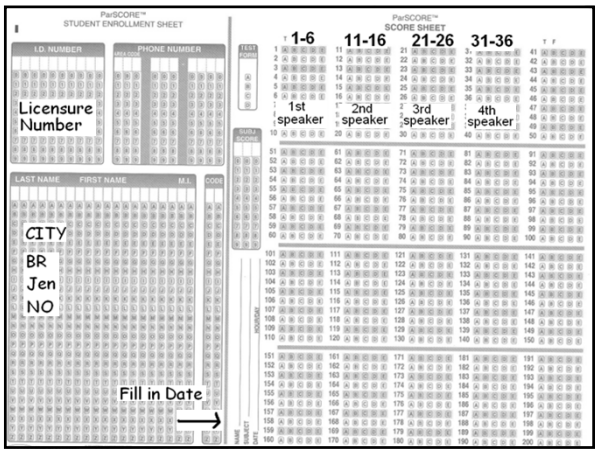


THERANOS: SCIENCE OR SCAM

Objectives

1. Discuss the history and current status of the company/laboratory Theranos – what do we know about testing using a single drop of blood.
2. Compare the roles of the FDA and CMS/CLIA in regulation of laboratories.

Who is Elizabeth Holmes? - on 2015 Lists

#121 Forbes 400 Richest in America
#6 America's Richest ($4.5 billion) Entrepreneurs under 40
#1 America's Self-Made Women
#72 Power Women
#360 Billionaires (world)

Elizabeth Holmes Founder & CEO Theranos

1984 Born in Washington DC
2002 Entered Stanford
chemical engineering
research pharmaceutical-chip technology
Summer – Singapore for SARS testing
Patent application
2003 Dropped out Stanford to start company-Theranos

Elizabeth Holmes Patents as of 2014 (Wikipedia)

In her name:
- 18 U.S.
- 66 non-U.S.

As co-inventor:
- >100 patent applicatications

What is Theranos?

- Private very secretive health care company
- Raised $400-750 million from investors
- Valued at $9 billion
- Contracts/Partners: Walgreens, Cleveland Clinic, Capital BlueCross in PA, HER vendor Practice Fusion

Theranos Mission

Source: www.Theranos.com

- Our mission is to make actionable information accessible to everyone at the time it matters.
- By making actionable information accessible to everyone in the world at the time it matters most, we are working to facilitate the early detection and prevention of disease, and empower people everywhere to live their best possible lives.

Theranos Intentions

- Low cost tests (half of Medicare/Medicaid reimbursement rates)
- Performed on portable instrument they developed for in-house use only—Edison
- Small volume sampling (in nanotainer; typically <150 microliters vs >1.5 mL)
- Patients have ready access to results

Nanotainer Collection Device

Source: www.theranos.com

Theranos Touts Transparency

- In Pricing: lists prices online at www.theranos.com

NO TRANSPARENCY IN TESTING

- Have not released any information about testing device—no peer-reviewed publications about technology

Theranos Board of Directors

From Wikipedia

- 2013: 3 directors (chem engineer; pharma & biotech executive; financier) left
- Current Directors have diplomatic or military backgrounds:
  - Henry Kissinger (sec of state)
  - William Perry (sec of defense)
  - George Schultz (sec of state)

Theranos Board of Directors

From Wikipedia

- Sam Nunn & Bill Frist* (Senators)
- Riley Bechtel (Bechtel Group chair BOD)*
- Richard Kovacevich (ex Wells Fargo CEO)
- William Foege (ex director of CDC)*
- General James Mattis (ret USMC)
- Admiral Gary Roughead (ret USN)

*added in 2014

Theranos Officers

- Elizabeth Holmes, Chairman, CEO and Founder
- Sunny Balwani: President and COO - Director; entrepreneur & computer scientist. Dropped out of Computer Science program at Stanford University. Worked for Lotus Development Corporation, Microsoft, started business-to-business ecommerce company

Theranos Timeline

- 2003 Company Founded as “Real-Time Cures” Early on claimed to be pharmacogenomics realm company
- 2005 Dr Ian Gibbons hired—produced 23 patents (19 with Holmes co-inventor)
- April 2012 Theranos opens CA lab in Palo Alto then later added 2nd CA lab in Newark

Theranos Timeline 2012

- Department of Defense evaluating system
- Official questioned technology and FDA inquiry looked into intent to distribute its tests without FDA clearance
- Theranos: didn’t need FDA approval-- it was a review for a military research project
- Holmes appealed to Gen. James Mattis to intervene

Theranos and Military

- Holmes met Mattis in 2011-- he wanted project -- testing in battlefield environment
- By June 2012 evaluation of Theranos testing apparently started
- July-August: A deputy director in regulatory & compliance launched inquiry including FDA

Theranos and Military

- Holmes asked Mattis to intervene & he sent request through channels
- Field demonstration never occurred
- June 2013 retired General Mattis joined Theranos's board of directors

Theranos Timeline: 2013

- May 2013 Dr. Gibbons commits suicide
- November 13, 2013: announces Walgreens agreement to open 42 "wellness centers" in Walgreens pharmacies in AZ (over next 2 years) plus 2 in CA and 1 in PA for samples collection & processing

Selected Test Costs from Current Test Menu (~200 tests offered)

		other labs
Basic Metabolic Profile	$5.76	$14-22.60
Blood Type (ABO/RhD)	$4.06	$10-24
CBC with auto differential	$5.29	$11-19
CBC with no differential	$4.41	$18.50
Comprehensive Metabolic Panel	$7.19	$17-27.40

Source: www.theranos.com

Selected Test Costs from Current Test Menu

hCG, urine pregnancy test	$4.31	$18-42
Hepatitis C (HCV) Genotype (details coming soon)	$117.96	
Ova and parasites	$6.06	$43
PT/INR	$2.68	$7-18
Urinalysis, Auto	$1.53	$19.50-23.50

Source: www.theranos.com

Theranos Timeline: 2014

- July 22: leases 20,000 sq foot space in Phoenix/Scottsdale area

Theranos Timeline: 2014

- December: Former employee complains to regulators that Edison device used for only 15 tests

Theranos Timeline: 2015

- February 17 JAMA editorial by Dr. John Ioannidis called upon Theranos to be more forthcoming about its equipment & testing methods—"stealth research"
- July 2: FDA approves HSV-1 test as waived test—announced July 16; waiver for HSV test and test system

Theranos CLIA waiver for HSV-1

Can put device (1 foot high, 1.5 feet wide, 2 feet deep with 8" x 5" touch pad; Edison?) offsite

Pursuing 120 other tests on same device

Picture here of Device

* BUT THERANOS HAS POLICY OF NOT ALLOWING DEVICE TO BE PHOTOGRAPHED

How To Operate Device
From Fortune.com 7/16/15 article

- Insert nanotainer into plastic cartridge (watch case size)
- Clicks if orientation correct
- Open front of analyzer using control pad
- Put cartridge ("like old VCR")
- Results wired by wifi, ethernet, cell- or satellite-phone to Theranos's databases

Analysis Time:
From Fortune.com 7/16/15 article

"The company says the potassium test ordinarily takes 20 minutes, while the Ebola test takes "more than an hour."

At the time Theranos was seeking emergency approval from FDA for its DNA-based Ebola test

Scottsdale AZ Lab Inspected by AZ DHS April 2, 2015

- Uses traditional instrumentation & venous blood (not nanotainer & Edison)

- Lab Director: Daniel Young, PhD engineering MIT – Vice President; specialty: dynamic modeling of biological systems

Scottsdale AZ Lab Inspected 4 Deficiencies Cited

- Proficiency Testing
- Instrument validation
- Humidity levels outside of acceptable limits
- Dating of blood-sample collections

Scottsdale AZ Lab Inspected Deficiencies Cited: PT

- Did not perform PT testing for ethsuximide, primidone, quinidine and tobramycin
- Stopped testing for these but failed to notify PT supplier & state regulators
- Cited Director for not meeting standards of "overall management & direction"

Scottsdale AZ Lab Inspected Deficiencies Cited: PT

Corrective Action:

1. Notified agencies
2. Hired supervisor to oversee proficiency testing

Deficiencies Cited: Instrument Validation

- Unable to provide back-up data showing full validation of 3 instruments
- Theranos: Validated instruments at Newark, CA lab before shipping to AZ; Manufacturers confirmed working properly but no data available

Deficiencies Cited: Instrument Validation

Corrective Action:

- Instruments validated (3rd time per Theranos) and data provided

FINAL INSPECTION OUTCOME: ALL CORRECTIVE ACTION ACCEPTED

May 5, 2015

- Announces addition of "reference lab"
- Apparent addition of Newark CA lab but not specified in announcement made at Pepperdine graduation speech by Holmes

Everything Going Good:

October 16, 2015
Wall Street Journal (WSJ)

"Hot Startup Theranos Has Struggled With the Blood-Test Technology"

By John Carreyrou

Included information from 4 former employees and others

October 16, 2015
Wall Street Journal (WSJ)

- Edison used for only 15 tests not all tests—performing 190 tests on traditional instrumentation
- Some physicians didn't trust results
- Dr. Gibbons widow says husband "told me nothing was working"
- PT samples tested on Edison & conventional instruments

PT Testing
Wall Street Journal (WSJ)

- Edison and conventional instruments gave different results for "vitamin D, 2 thyroid hormones and prostate cancer"
- Mr. Balwani ordered personnel to report PT results from other instruments and to use Edison for those 4 tests for patients
- Formal complaint April 2014 to New York State Department of Health

Patient Testing
Wall Street Journal (WSJ)

- About 60 of tests run on traditional instruments used special dilution methods causing results to fall below approved ranges
- Former employees claim some K results critically high
- Article cites other examples of abnormal Theranos results followed by normal results from other labs

Theranos Responses to WSJ

- Edison use: "not using for all tests"; won't say how many citing "trade secrets"
- Did delete from website: "Many of our tests require only a few drops of blood" and "usually only 3 tiny micro-vials per sample"
  - Reason given: "for marketing accuracy"

Theranos Responses to WSJ

- PT testing: on "left-over PT samples"; unique technology has no peer group and thrown off by preservatives in PT
- Dilution: "methods for preparing samples for analysis are trade secrets and cannot be revealed

Theranos Proficiency Testing

From Theranos website as of 4/19/16

"Theranos undergoes continuous proficiency testing on blinded samples from leading organizations, including the College of American Pathologists (CAP) and the American Proficiency Institute (API). "

Theranos Proficiency Testing

From Theranos website as of 4/19/16

"To date in 2015, Theranos Proficiency Testing met or surpassed performance goals 98% of the time for CAP and API across hundreds of assays. Theranos is leading the lab industry in transparency by publishing Proficiency Testing performance statistics."

October 16, 2015

Theranos suspends use of its proprietary finger-prick blood collection device nanotainer in response to questions raised by FDA.

FDA Report October 27, 2015

- Had inspected 2 Theranos CA labs (Palo Alto & Newark) from August 25 to September 16th
- Results in report:
  1. Theranos nanotainer an "uncleared medical device"
  2. Deficiences in Theranos' quality-assurance processes such as supplier qualifications

FDA and the Laboratory

- Questionable whether FDA can regulate direct to consumer testing since tests aren't drugs, vaccines or medical devices
- For consumer genetics testing FDA warned 23andMe using saliva collection device as "medical device"

FDA and Testing

- Companies submit testing instruments and the tests on those instruments for approval in order to be able to sell to labs
- Theranos (and genetics companies) claim they don't have to be FDA approved for direct to consumer testing BUT Theranos did submit many tests and its Edison to FDA

FDA and Testing

- Laboratory Developed Tests (LDTs)--FDA hasn't made its final ruling
- Theranos tests would conceivably be LDTs when performed on Edison and maybe on conventional instrumentation if don't follow manufacturer's recommendation for sample (not diluting routinely, etc)

November 2015

- Theranos seeks to hire Laboratory Director
- Current Director: Dr. Sunil Dhawan, a dermatologist (21 yrs supervising lab affiliated with his dermatology practice)
- By January 2016 hired Kingshuk Das, MD (also associate med director of UCLA clinical labs) and a Technical Consultant

December 20, 2015

- Wall Street Journal reports that Theranos is being investigated by CMS and by the FDA due to complaints by 2 former employees
- Complaint to CMS: company aware of Edison's inaccurate results since 2013
- Complaint to FDA: company under reported frequency of Edison breaking down

Related Article Published December 2015

Can You Use Fingerprick Blood for All Tests?

Drop-to-Drop Variation in Components of Fingerprick Blood

- Ref. Bond MM, Richards-Kortum RR. Drop-to-Drop Variation in the Cellular Components of Fingerprick Blood. Am J Clin Pathol, 2015; 144: 885-894.
- Department of Bioengineering, Rice University, Houston TX

Goals of Study: DETERMINE

- Drop-to-drop variability in blood parameters obtained from fingerprick blood
- Minimum volume of blood needed to reduce variability to acceptable levels for clinical decision making (ex. Anemia)

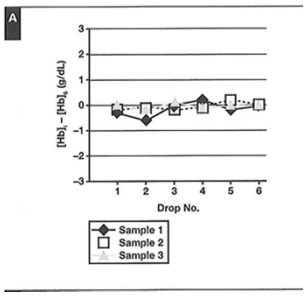
Study: Drop-to-Drop Variation in Components of Fingerprick Blood

- 11 donors (14 recruited; 3 rejected because of milking or clots); 1 fingerprick
- Wipe away 1st drop; collect 6 successive drops (20 microliter capillary tubes)
- Measured: Hgb, total WBC count, 3-part WBC differential, platelet count on Beckman Coulter AcT diff2

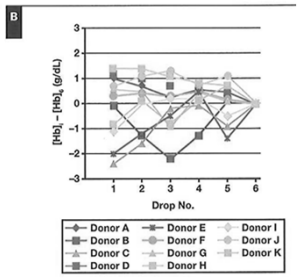
Study: Drop-to-Drop Variation in Components of Fingerprick Blood

- CBC results compared to results from venous blood drawn before fingerstick
- Also compared drop-to-drop variation in hemoglobin measured on POCT HemoCue 201+ ; 10 successive drops-- 10 microliter samples collected directly into HemoCue cuvette

RESULTS Hgb: 6 Drops Venous Blood

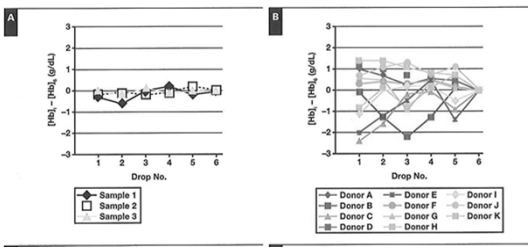


RESULTS Hgb: 6 Drops Fingerprick



Normalized by subtracting Hgb of last drop from each in order eliminate baseline differences in donors Hgb

RESULTS: 6 Drops Venous vs Fingerprick Blood



RESULTS: CV Variation in Hgb for Venous vs Fingerprick

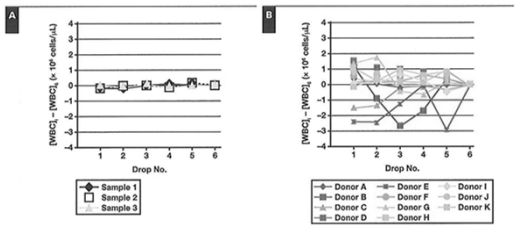
Table 1
Hemoglobin Concentration Measured Using Hematology Analyzer*

Characteristic	Successive 20-µL Drops of Venous Blood			Successive 20-µL Drops of Fingerprick Blood, Average
	Sample 1	Sample 2	Sample 3	
Mean (SD)	14.8 (0.28)	9.5 (0.15)	7.1 (0.10)	0.59
%CV	1.9	1.6	1.3	4.4
Range	0.8	0.4	0.3	1.6

CV, coefficient of variation.
* The left side of the table shows the mean (SD), percent CV, and range (maximum – minimum hemoglobin value) of the hemoglobin concentration of samples depicted in Figure 1A (venous blood) in g/dL. The right side of the table shows statistics for the hemoglobin concentration of samples depicted in Figure 1B (fingerprick blood). For the fingerpricks, measures were calculated for six drops collected from one fingerprick of each donor, then averaged for all donors.

CONCLUSION: average CV for successive drops of fingerprick blood for Hgb analysis was between 2.3 and 3.4 greater than for small volumes of venous blood

Results for WBC



WBC & 3-Part Differential CVs

Table 2
WBC Concentration and Three-Part Differential Measured Using a Hematology Analyzer[a]

Characteristic	Successive 20-µL Drops of Venous Blood: Sample 1	Sample 2	Sample 3	Successive 20-µL Drops of Fingerprick Blood, Average
WBC concentration, $\times 10^6$ cells/µL				
Mean (SD)	6.8 (0.10)	6.5 (0.13)	4.8 (0.11)	0.60
%CV	1.5	2.1	2.2	8.6
Range	0.3	0.4	0.3	1.6
Lymphocyte count, $\times 10^6$ cells/µL				
Mean (SD)	1.7 (0.04)	1.5 (0.08)	1.2 (0.05)	0.18
%CV	2.4	5.1	4.3	7.2
Range	0.1	0.2	0.1	0.5
Granulocyte count, $\times 10^6$ cells/µL				
Mean (SD)	4.8 (0.06)	4.8 (0.15)	3.4 (0.08)	0.42
%CV	1.3	3.1	2.2	10
Range	0.2	0.4	0.2	1.1
Monocyte count, $\times 10^6$ cells/µL				
Mean (SD)	0.3 (0.05)	0.2 (0.05)	0.1 (0.05)	0.08
%CV	21.9	36.5	37.4	30
Range	0.1	0.1	0.1	0.2

CV, coefficient of variation.
[a] The left side of the table shows the mean (SD), percent CV, and range (maximum – minimum value) of the samples depicted in Figure 2A (venous blood). The right side of the table shows statistics for samples shown in Figure 2B (fingerprick blood). For the fingersticks, measures were calculated for six drops from one fingerprick of each donor, then averaged for all donors.

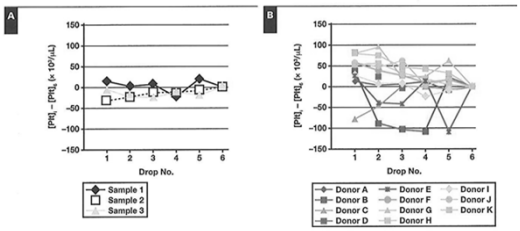
CONCLUSION: WBC & 3-Part Differential CVs

Average CV for successive drops of fingerprick blood was higher than that of venous blood controls for parameters by amount shown below:

WBC	3.9 to 5.7 times higher
Lymphocytes	1.4 to 3.0 times higher
Granulocyte	3.2 to 7.7 times higher

Hard to compare monocytes because of low absolute counts

Results for Platelets



Variation in Platelets Measurement

Table 3
Platelet Count Measured Using a Hematology Analyzer[a]

Characteristic	Successive 20-µL Drops of Venous Blood: Sample 1	Sample 2	Sample 3	Successive 20-µL Drops of Fingerprick Blood, Average
Mean (SD)	316 (14.6)	238 (11.4)	199 (9.5)	31.9
%CV	4.6	4.8	4.8	19
Range	42	32	25	80

CV, coefficient of variation.
[a] The left side of the table shows the mean (SD), percent CV, and range (maximum – minimum platelet value) of the platelet count ($\times 10^3$/µL) of samples depicted in Figure 3A (venous blood). The right side of the table shows statistics for the platelet count of samples depicted in Figure 3B (fingerprick blood). For the fingersticks, measures were calculated for six drops collected from one fingerprick of each donor, then averaged for all donors.

CONCLUSION: average CV for successive drops of fingerprick blood for platelet analysis was 4 times greater than for small volumes of venous blood

Study: Drop-to-Drop Variability on POCT Device

7 donors

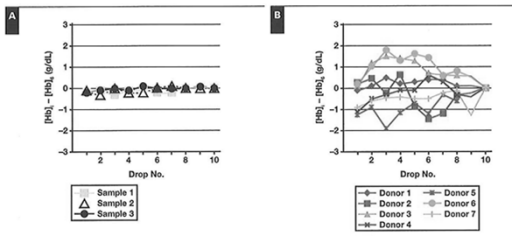
1 drop wiped away

10 successive drops (~10 microliters each)

Analyzed on POCT hemoglobin analyzer (HemoCue 201+)

Analyzer variability determined using venous blood

Results for POCT Hgb



Results for POCT Hgb

Table 4
Hemoglobin Concentration Measured Using a Point-of-Care Device[a]

Characteristic	Successive 10-µL Drops of Venous Blood			Successive 10-µL Drops of Fingerprick Blood, Average
	Sample 1	Sample 2	Sample 3	
Mean (SD)	14.2 (0.10)	9.8 (0.13)	5.9 (0.09)	0.49
%CV	0.7	1.3	1.6	3.5
Range	0.3	0.4	0.3	1.6

CV, coefficient of variation.
[a] The left side of the table shows the mean (SD), percent CV, and range (maximum – minimum hemoglobin value) of the samples depicted in Figure 4A (venous blood) in g/dL. The right side of the table shows statistics for the samples depicted in Figure 4B (fingerprick blood). For the fingersticks, measures were calculated for the collection of drops from one fingerprick of each donor, then averaged for all donors.

CONCLUSION: average CV for successive drops of fingerprick blood for Hgb was 2.2 to 5 times higher than for small volumes of venous blood

STUDY CONCLUSIONS

These data suggest caution when using measurements from a single drop of fingerprick blood.

STUDY CONCLUSIONS

For clinical decision making, we recommend using fingerprick blood to assess hemoglobin or WBC concentration only when the degree of variability is acceptable.

Our data suggest caution in using small volume sample devices for Hgb and WBC tests for clinical decision making, such as determining anemia status.

BACK TO OUR STORY

Meanwhile back at Theranos

CMS LETTER TO CA LAB JANUARY 2016 re November CMS survey

CMS LETTER TO CA LAB JANUARY 2016

January 25, 2016

Sunil Dhawan, M.D., Director
Theranos, Inc.
7333 Gateway Boulevard
Newark, CA 94560

CLIA Number: 05D2025714

RE: CONDITION LEVEL DEFICIENCIES – IMMEDIATE JEOPARDY

Dear Dr. Dhawan:

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. 263a) and 42 Code of Federal Regulations, Part 493 (42 CFR 493). Federal regulations require onsite surveys to determine whether or not a laboratory is in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

The Centers for Medicare & Medicaid Services (CMS) conducted a CLIA recertification and complaint survey of the laboratory. The onsite survey was completed on November 20, 2015.

CMS LETTER TO CA LAB JANUARY 2016

complaint survey of the laboratory. The onsite survey was completed on November 20, 2015. However, the survey concluded with the receipt of critical information received from the laboratory on December 23, 2015. As a result of the survey, it was determined that your facility is not in compliance with all of the Conditions required for certification in the CLIA program. In addition, based on the Condition-level requirement at 42 C.F.R. § 493.1215, Hematology, it was determined that the deficient practices of the laboratory pose immediate jeopardy to patient health and safety. (Immediate jeopardy is defined by the CLIA regulations as a situation in which immediate corrective action is necessary because the laboratory's non-compliance with one or

Deficiencies Cited

injury or harm, or death, to individuals served by the laboratory or to the health and safety general public.) Specifically, the following Conditions were not met:

D5024: 42 C.F.R. § 493.1215	Condition: Hematology;
D5400: 42 C.F.R. § 493.1250	Condition: Analytic systems;
D6076: 42 C.F.R. § 493.1441	Condition: Laboratories performing high complexity testing; laboratory director;
D6108: 42 C.F.R. § 493.1447	Condition: Laboratories performing high complexity testing; technical supervisor; and,

Later Information Reported about This Inspection Report

- Theranos failed to adequately correct 43 of 45 deficiencies cited
- 1 deficiency: failure to provide evidence that corrected reports sent to patients who got flawed test results
- 1 article speculates that Hematology Deficiency cited was for erroneous PT results

Jan 24, 2016 *Wall Street Journal*

- Reports on CMS inspection deficiencies
- Theranos told Walgreens its outsourcing highly complex tests to UCSF & ARUP
- Since mid-November Theranos sent >1200 tests to UCSF
- UCSF charges Theranos >$300 for comprehensive metabolic profile – Theranos charges $7.19 at sites

January 29, 2016

- Walgreens suspends service in Palo Alto store and directs Theranos to do all testing from any Walgreens store in AZ lab or to an accredited outside lab
- Capital BlueCross stops drawing blood in PA retail store
- Cleveland Clinic says no study of Thernos vs other labs has begun

Only Peer Reviewed Article Concerning Theranos

March 30, 2016 The Journal of Clinical Investigation (JCI)

Authors from Mt. Sinai Hospital, NY

60 Healthy Adults (19-71yo); 4 collections in 6.5 hrs (venipuncture VP;fingerstick FS;FS;VP)

22 Tests: CBC; Lipid Panel; Chemistry

3 Labs: LabCorp (Phoenix); Quest (Tempe & San Juan Capistrano); Theranos

Kidd BA et al. Evaluation of direct-to-consumer low-volume lab tests in healthy adults. JCI doi:10.1172/JCI86318

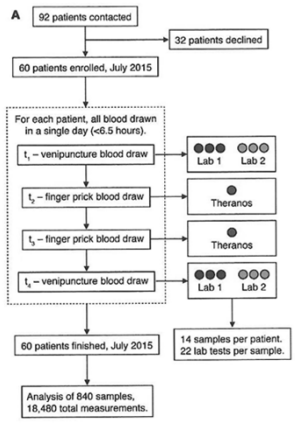
22 Tests (*4 calculated) Requiring Small Sample Volumes:

CBC: RBC, WBC, Hgb, hct*,MCV, MCH*, MCHC*, RDW*, Plt, Neut, Lymph, Mono, Eosin, Baso

Lipids: total cholesterol, LDLc, HDLc, triglycerides

CRP, Phosphate, Uric Acid, T bilirubin

Kidd BA et al. Evaluation of direct-to-consumer low-volume lab tests in healthy adults. JCI doi:10.1172/JCI86318



Study Design & Sample Collection

Samples collected in Phoenix, AZ

Kidd BA et al. Evaluation of direct-to-consumer low-volume lab tests in healthy adults. JCI doi:10.1172/JCI86318

Results

- Theranos sample collection has higher sample rejection rates
- Theranos reports more measures outside their normal range
- Testing services show nonequivalent test results
- Intersubject & interservice variability dominate lab test results

Kidd BA et al. Evaluation of direct-to-consumer low-volume lab tests in healthy adults. JCI doi:10.1172/JCI86318

Results: Theranos sample collection has higher sample rejection rates

Theranos rejected sample 12.5 times more than LabCorp or Quest

Theranos returned missing data for 4 of 6 subjects; LabCorp returned missing data for 1 subject

Kidd BA et al. Evaluation of direct-to-consumer low-volume lab tests in healthy adults. JCI doi:10.1172/JCI86318

Results: Theranos reports more measures outside their normal range

Percentage of results reported outside of lab's reference range:

LabCorp	8.3%
Quest	7.5%
Theranos	12.2%

Kidd BA et al. Evaluation of direct-to-consumer low-volume lab tests in healthy adults. JCI doi:10.1172/JCI86318

Results: Theranos reports more measures outside their normal range

Theranos 1.6 times more likely to report abnormal result than other 2 labs

This ratio ranged from 1.6 (LDL chol) to 4.5 (lymphocyte counts)

Kidd BA et al. Evaluation of direct-to-consumer low-volume lab tests in healthy adults. JCI doi:10.1172/JCI86318

Results: Testing services show nonequivalent test results

CBC results

LabCorp consistently lower for WBC & hct

Theranos higher neutrophils & monocytes

MCHC and RDW different for all 3 labs

Kidd BA et al. Evaluation of direct-to-consumer low-volume lab tests in healthy adults. JCI doi:10.1172/JCI86318

Results: Testing services show nonequivalent test results

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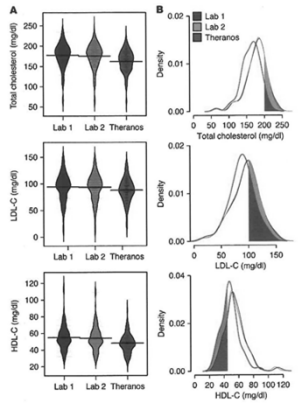


Lipid results: Theranos lower for total Cholesterol, HDLc, and LDLc

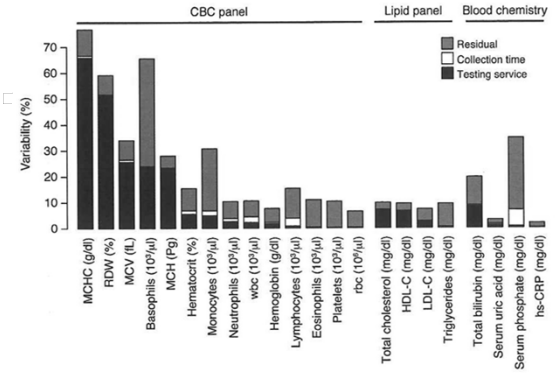
Results: Intersubject & interservice variability dominate lab test results

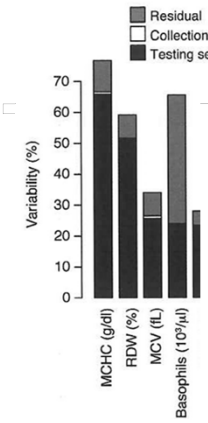
Looked at 4 sources of variability:

- *Subject
- *Testing service (lab)
- Collection Time
- Technical Reproducibility

* Greatest variability

Kidd BA et al. Evaluation of direct-to-consumer low-volume lab tests in healthy adults. JCI doi:10.1172/JCI86318





correlation. For example, consider the lab test for MCHC. Variation across testing service explains 65% of the overall observed variance. This result is equivalent to saying that, after correcting for the effects of subject and collection time, the correlation between samples from different services is 65%.

April 7, 2016 Theranos Announces Scientific & Medical Advisory Board

- 8 well recognized and respected laboratory and medical experts
- Includes 4 former Presidents of AACC
- Former Director of CDC
- 3 review sessions held during which attendees reviewed R&D reports including assay validations

April 13, 2016 news

CMS letter of March 18th it was considering:

- Revoking CLIA certificate
- Fining Theranos up to $10,000/day
- Suspending or cancelling approval to receive Medicare payments
- Banning Holmes, Balwani,& Dhawan from owning or operating a clinical lab for 2 years

Note: Sanction letter not released while CMS reviewing Theranos request for redaction of trade secrets

Ban Considered: from owning or operating clinical lab for 2 yrs

Elizabeth Holmes--Founder/CEO

Ramesh Sunny Balwani-Owner/President/COO

Dr. Sunil Dhawan-former Medical Director

Status to Date

Theranos had 10 days to respond to March 18 letter and they responded

CMS reviewing response

April 19, 2016
New York Times and Bloomberg

- Theranos under criminal investigation
- by Security and Exchange Commission & US Attorney's Office for Northern Calif
- Walgreens and NY State Department of Health received subpoenas
- Some people said investigation is whether Theranos misled government officials

Appeals Process If Ban Upheld

- Some sanctions take effect within 8 days
- Revoking CA license could take 60 days
- If appeal keep license through appeal
- Appeals to administrative law judege & then departmental appeals board
- CMS has not lost a case like this from 2001 to end of 2010

April 18, 2016 Maria Shriver Interviews Holmes on Today Show

- "I feel devastated"
- "Taken approach to rebuild lab from start"
- Brought in new Lab Director and Advisory Board

Theranos CEO Elizabeth Holmes to Speak at 68th AACC Annual Scientific Meeting and Clinical Lab Expo

Company founder to present data on technology

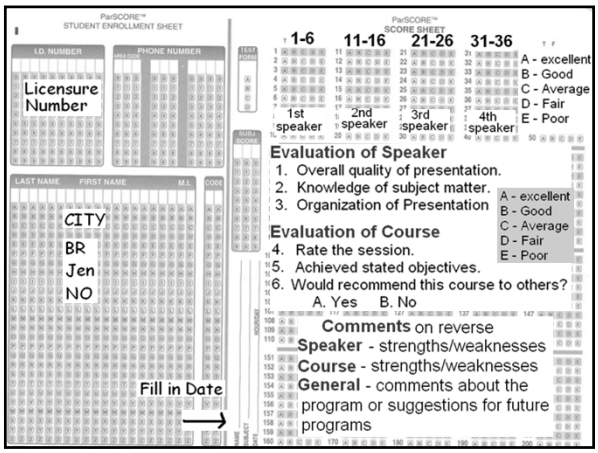
Date: APR.21.2016 // Source: CLN Stat

Elizabeth Holmes, CEO of the startup lab testing company, Theranos, will speak during a special session at the 68th AACC Annual Scientific Meeting & Clinical Lab Expo in Philadelphia. For the first time, Holmes will present data that clearly lays out how Theranos's technology works to process the full range of laboratory tests from a few drops of blood. She also will answer questions from scientific experts at the conclusion of her talk.

SCIENCE OR SCAM? TO BE CONTINUED

Questions

Thank you for your attention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1st speaker
2nd speaker
3rd speaker
4th speaker
A - excellent
B - Good
C - Average
D - Fair
E - Poor
Evaluation of Speaker
1. Overall quality of presentation.
2. Knowledge of subject matter.
3. Organization of Presentation
Evaluation of Course
4. Rate the session.
5. Achieved stated objectives.
6. Would recommend this course to others?
A. Yes B. No
A - excellent
B - Good
C - Average
D - Fair
E - Poor
Comments on reverse
Speaker - strengths/weaknesses
Course - strengths/weaknesses
General - comments about the program or suggestions for future programs