

# Can Theranos Disrupt the Clinical Lab Testing Market: An Objective Look at Advantages, Liabilities and Challenges that must be addressed

Robert Boorstein, MD, PhD

Founder and Director

ClasGroup

Presentation at the Executive War College

New Orleans , LA

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## Elizabeth Holmes, Who Wants To Shake Up The Blood Testing Industry, Is A Billionaire At 30



**Zina Moukheiber**  
CONTRIBUTOR

I cover health IT and Middle Eastern billionaires.

**FULL BIO**

*Opinions expressed by Forbes Contributors are their own.*

FOLLOW

Elizabeth Holmes who developed a way to quickly diagnose a few drops of blood with minimal draw at a fraction of the price of commercial labs, is a billionaire.



# Learning Objectives for this presentation

- 1) Understand the opportunities that Theranos sees in the clinical laboratory market.
- 2) Understand the advantages that Theranos claims will support its ability to take advantage of these opportunities.
- 3) Critically assess the ability of Theranos to achieve stated goals.

# Pretest

1. With regard to my knowledge of the Theranos business model, I consider myself
  - A. Very familiar
  - B. Somewhat familiar
  - C. Slightly familiar
  - D. Not at all familiar
2. I view the threat of Theranos to my business to be
  - A. Very significant
  - B. Somewhat significant
  - C. Slightly significant
  - D. I do not view Theranos as a threat.

# Theranos claims to revolutionize the industry

Promotion versus reality

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# theranos

the blood tests that need just a tiny sample.

**Walgreens partners with Theranos to provide lab services**

Theranos is working to shape the future of lab testing. Now, for the first time, their high-complexity CLIA-certified laboratory can perform your tests quickly and accurately using tiny samples.<sup>1</sup>

[Learn more at Theranos.com](#)

[Para información en español haga clic aquí](#)

# Theranos makes broad highly publicized claims

- Faster
- Less Intrusive—uses fingerstick samples
- Widely available through partnership with Walgreens
- Cheaper (and transparently so) with insurance coverage or self pay.
- Uses revolutionary technology

## One tiny drop will change the world.

Theranos gives you precise results in a matter of hours, equipping you with actionable information when you need it. We can help you make fast diagnoses, start triage and treatment quickly, and help you help your patients with the confidence of knowing.

Our lab:







## A new kind of patient care.

With Theranos, you can offer your patients advanced, cutting-edge healthcare. From a friendlier blood draw, to fast results, to convenient lab options, you can now give your patients the kind of care you want to provide.

THERANOS RATES ARE ALWAYS

LESS  
THAN **50%**

OF MEDICARE RATES

**Covered and affordable.**

We're committed to making lab testing more accessible to everyone. That means pricing our tests at dramatically low rates. We can accept major insurance carriers as well as Medicare and Medicaid. And if you're uninsured, we offer you the same discounted prices we offer everyone else. Because a test should cost the same, no matter who you are.

## A few drops is all it takes.

Theranos' patented technology can analyze samples as small as 1/1,000 the size of the typical blood draw. Our tests are certified in our CLIA laboratory and cover a full range from blood, urine, and other samples. It's fast, easy, and the highest level of quality.

## Fast results. Fast answers.

Our proprietary infrastructure allows us to perform our test analyses with unprecedented speed. So we can have results to you and your doctor in a matter of hours, not days. Which means a fast diagnosis to support better, more informed treatment.

## High levels of precision.

By systematically controlling and standardizing our micro-processes, we offer tests with high levels of precision. We've also automated our pre- and post-analytic processes, minimizing human processing — the cause of the majority of lab-test errors.

# Theranos claims have received massive attention in multiple media sectors.

- Traditional print
- Digital media
- Tech/Silicon Valley Media outlets
- Financial Press
- Clinical Laboratory Trade Publications

# THE WALL STREET JOURNAL.

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<http://www.wsj.com/articles/SB10001424127887324123004579055003869574012>

THE WEEKEND INTERVIEW

## Elizabeth Holmes: The Breakthrough of Instant Diagnosis

A Stanford dropout is bidding to make tests more accurate, less painful—and at a fraction of

[Medscape](#) > [Eric Topol on Medscape](#) > [Medscape One-on-One](#)

# Creative *Disruption*? She's 29 and Set to Reboot Lab Medicine

Elizabeth Holmes plans to revolutionize testing by using tiny blood draws and offering near-instantaneous results

[Eric J. Topol, MD](#), Elizabeth Holmes | [Disclosures](#)

November 18, 2013

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## Cover Story

### Theranos: The biggest biotech you've never heard of

Firm sees stealth as a competitive advantage while it works to bring a revolutionary medical device to market

SUBSCRIBER CONTENT: Aug 30, 2013, 3:00am PDT



WIRED


SUBSCRIBE

CATLIN ROPER SCIENCE 02.18.14 1:30 PM

THIS WOMAN INVENTED A WAY TO RUN  
30 LAB TESTS ON ONLY ONE DROP OF  
BLOOD

## Selected Media Citations 2015

Source: [www.Theranos.com](http://www.Theranos.com),  
4/21/2015

CBS This Morning: Blood, Sweat & No Fear 

TIME 100: The Most Influential People in the World in 2015

USA Today: Arizona health law could boost Theranos' bio-tech prospects

The Arizona Republic: Patients can soon get lab tests without doctors' orders

The New York Times: The Healing Power of Your Own Medical Records

Fortune: 9 of the most inspiring acts of leadership

Inc.: How Elizabeth Holmes Became America's New Entrepreneurial Icon

Glamour: Career Advice From Theranos Founder Elizabeth Holmes

Fox Business: Theranos, Cleveland Clinic CEO's on innovation partnership

The Arizona Republic: Tech company Theranos pushes consumer lab-testing bill


Fast Company: Most Innovative Companies 2015


Inc.: Elizabeth Holmes Is a Beacon for Female Entrepreneurs 

8th Annual Crunchies Awards: Best Health Startup 

Brand Channel: Breakthrough Branding: Theranos, with Walgreens, Revolutionizes Healthcare

Clinton Foundation: Health Matters 

Stanford Graduate School of Business: View From the Top 

ABC15: Score big savings on your lab tests with Theranos 

## Bloody Amazing

*This story appears in the July 21, 2014 issue of Forbes.*

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Elizabeth Holmes, 30, is the youngest woman to become a self-made billionaire—and she's done so four times over. In 2003, as a Stanford undergrad, she founded Theranos, a Palo Alto company that's disrupting the business of blood testing, replacing the services provided by giants like Laboratory Corp. of America and Quest Diagnostics. "What we're about is the belief that access to affordable and real-time health information is a basic human right, and it's a civil right," she says .

Theranos has raised approximately \$400 million, with a recent round valuing it at \$9 billion—more than the market caps of any of her rivals. Holmes holds 50% of the stock, putting her net worth at \$4.5 billion. With just a drop of blood Theranos can do the same tests that used to require vials of it, at lower cost. "It's one of those white-whale type of approaches, where if this were to become mainstream, then the entire diagnostic testing market would turn over," says Mike Cherny, the diagnostics analyst at International (<http://www.forbes.com/international/>) Strategy & Investment.



# Publication in Forbes raises profile in financial community

Market value of \$ 9 billion comparable to that of Labcorp and Quest

	Market Value (billions)	Employees	Revenue per req	Revenue (millions)
Theranos	\$9	700	\$ 25 <i>est</i>	\$10-30 <i>est</i>
Labcorp	\$12.6	45000	\$44	\$ 6,011
Quest	\$11.0	36500	\$44	\$ 7,435

Sources: Laboratory Economics, Yahoo finance, as of 4/21/2015.

# What is a unicorn?

- They're called “unicorns”—companies that have soared to a \$1 billion valuation or higher, based on fundraising. The billion-dollar tech startup was once the stuff of myth, but now they seem to be everywhere, backed by a bull market and a new generation of disruptive technology.

FORTUNE



# Theranos looks more like a high tech Unicorn than a biotech lab startup

## Recent lab IPO's

	Market Value (millions)	Revenue (millions)
THERANOS	<b>\$9,000</b>	<i>\$10-30 est</i>
Invitae	\$429	<i>\$1.60</i>
Exact	\$1,970	<i>\$1.80</i>
Nanostring	\$225	<i>\$47.60</i>

## Well known Unicorn companies

	Market Value (billions)	Revenue, estimated (millions)	Unicorn Rank, Fortune (January 2015)
Uber	41.20	10000	2
Airbnb	13.00	500	4
Dropbox	10.40	400	6
Snapchat	19.00	0.0	7
Theranos	9.00	20.0	9

Sources: Fortune, Yahoo finance, as of 4/21/2015.

# Even trade publications were supportive of the Theranos approach

## **Inside the Diagnostics Industry**

### Theranos Aims to Transform the Medical Diagnostic Industry



Elizabeth Holmes,  
Founder and CEO,  
Theranos

**A**fter years of speculation, Theranos (Palo Alto, Calif.) last fall unveiled its revolutionary plan to reshape the future of laboratory testing. With a laser-sharp focus on lowering testing costs (always 50 percent or below Medicare reimbursement rates) and standardizing quality, the company's plans potentially hold benefits for stakeholders across the health care industry.

Patients benefit from the convenience of Theranos draw centers in Walgreens pharmacies and from the company's proprietary and patented infrastructure for processing microsamples (one-one thousandth the size of a typical blood draw). The company believes its quick return of precise results will provide enhanced efficiency and informative, longitudinal value for physicians and pathologists. Theranos also poses a disruptive threat to the laboratory industry through a transformative emphasis on transparency reflected in the company's commitment to both price transparency (all test prices are on the company's Web site) and publication of margin of error variation for aiding interpretation of test results.

The company's goal of deploying a national network of accessible testing centers is becoming a reality with the expansion of its Walgreens-based Wellness Centers to the Phoenix area in mid-November 2013, following the opening of the first center in Palo Alto in September 2013. Elizabeth Holmes, Theranos's founder and CEO, recently spoke to *DTET* about the unique infrastructure powering the company's pioneering vision.



## **Diagnostic Testing & Emerging Technologies**

*"With new customer paradigms, laboratories need to evaluate where they will fit in."*

—Robert Boorstein,  
M.D., Ph.D.

"It is a national footprint with a robust information management system," says Robert Boorstein, M.D., Ph.D., director of the laboratory consulting firm ClasGroup (New York). "Doctors are already used to ordering prescriptions online and patients are used to going there to pick up their prescriptions ... Spreading out demand will affect labor costs and be much more efficient than standalone draw stations."

Boorstein predicts much like Amazon is changing the retail model through use of technology and new distribution methods, laboratories need to think outside of the box for wholly new models.

"With new customer paradigms, laboratories need to evaluate where they will fit in," says Boorstein. "It is hard to envision the logic of freestanding draw centers at some point. Why would you need separate facilities if draws can be done at drug stores up to 24 hours a day?"

## Ignoring Lab Industry, Theranos Goes Its Way

➤ Unknown to the wider clinical laboratory industry this emerging laboratory test firm has disruptive plans

➤➤ **CEO SUMMARY:** With each passing month, Theranos pulls open the curtain a bit more on its business structure and its market growth plans. Its clinical lab tests are now offered in Walgreens pharmacies in Palo Alto, California, and Phoenix, Arizona. Recent news coverage in *Fortune* and *USAToday* disclosed that company officials—based on stock sales to date—value the company at \$9 billion. That's more than the market value of the shares of Quest Diagnostics or LabCorp.

## My Visit to Walgreens For Theranos Lab Tests

➤ Secretive lab test company is getting profiled by national the press, but is it delivering to patients?

➤➤ **CEO SUMMARY:** One of the biggest unknowns in the lab testing industry today is Theranos, the lab testing company based in Palo Alto, California. It says its proprietary technology is poised to transform the lab testing experience for patients and physicians. It says it can perform hundreds of lab tests, using a finger stick collection with a micro-specimen and return results in four hours. Here is the actual experience of your DARK REPORT editor, who had Theranos perform lab tests for him and his physician.

By Robert L. Michel

■ ■ ANY CLINICAL LAB EXECUTIVES and

its proprietary diagnostic technology for use in clinical settings? What is its strategy to meet federal and state laws and regula-



## ***Pathologist Raises Questions about Theranos' Business Model***

- What I had envisioned.
  - Seamless electronic ordering of lab tests
  - Rapid friction free blood draws and payment (like Starbucks or Uber).
  - Rapid delivery of results.
  - Efficient use of personnel and space.
- Obstacles to delivery
  - Central lab testing, not point of service.
  - Difficulties with finger stick collections.
  - High labor costs/low utilization.
  - Regulatory barriers.
  - No real leap in information management
  - Payment/reimbursement

# Current Status of the Theranos model

Theory vs. Reality



# What is the current operational model?

- Specimens are collected at draw stations within 40 Walgreens in Phoenix area in Arizona.
- Largely, but not entirely, collected with fingersticks
- Specimens initially shipped to CLIA laboratory in Palo Alto.
  - Samples now processed in new laboratory in Scottsdale.
  - Limited services in California
- Results available in 1-3 days on Theranos website.

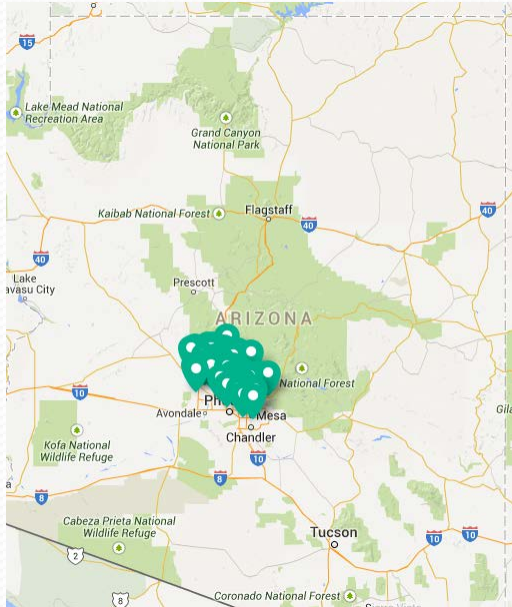


# Does the current operational model disrupt existing laboratory services?

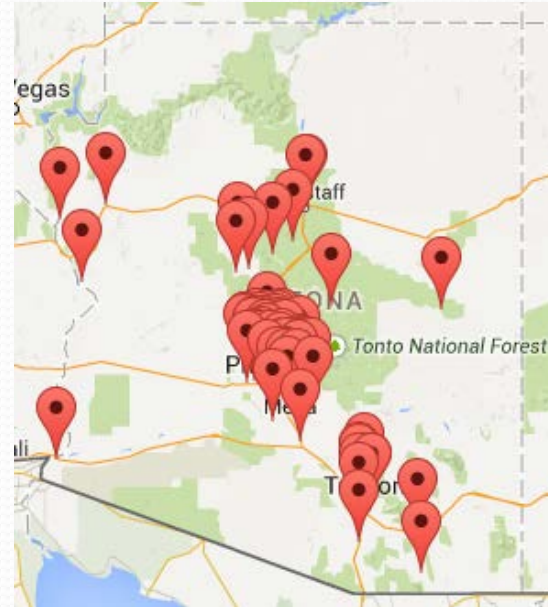
- Availability of draw stations.
- Utilization of finger sticks.
- Turnaround time.
- Price transparency.
- User experience.

# Availability of draw stations in Arizona

## Theranos



## Sonoma-Quest



# Is the micro-sample a new and compelling standard?

the lab test, reinvented.

## MICRO-SAMPLE

No more huge vials to fill. At Theranos, we only need a few drops.



## NANOTAINER™

0.508 in

Our nanotainer™ tube is smaller than a dime.

# Is the micro-sample a new and compelling standard?

## The claim

### A few drops is all it takes.

Theranos' patented technology can analyze samples as small as 1/1,000 the size of the typical blood draw. Our tests are certified in our CLIA laboratory and cover a full range from blood, urine, and other samples. It's fast, easy, and the highest level of quality.

## The reality

- No published data on the use by Theranos of fingersticks vs traditional phlebotomy.
- Published anecdotal reports (Dark Report, Laboratory Economics) report frequent use of traditional phlebotomy.

# Is the micro-sample a new and compelling standard?



★★★★★ 1/22/2015

the Theranos counter was quick. All my 7 tests and panels qualified for the finger prick method ( I had called their customer support to verify this beforehand).

Theranos has their own waiting room and blood draw room. It was a relaxing environment. A large screen TV showed tropical fish swimming to the sound of soothing music. The technician explained the process, a heat pad was applied to my left hand and middle finger, and a device executed a painless prick to the tip of my middle finger. The technician gently squeezed my finger to extract a small amount of blood. The process was quick, painless, and much easier than a traditional blood draw.

★★★★★ 11/29/2014

To preface my review, the man who did my blood test was FANTASTIC, had a wonderful bedside manner, super professional, and made the experience as painless as possible.

I am aware that Theranos is a new technology and that not all tests are offered through them, however, there should be more education for doctors sending their patients here--none of the tests I was having done were able to be done via a finger stick, all had to be done via a traditional blood draw.

★★★★★ 11/11/2014 • Previous review

My boyfriend found out about this for me and so I drove all the way from SF to Palo Alto because I needed some lab-work done. The Walgreen's part of the experience was disappointing. I waited in a long line of people who were filling prescriptions even though there was an unmanned dedicated Theranos check-in window. After nearly a half hour in queue, my lab paperwork was processed and I was sent to the Theranos waiting room, which was very nice. The technician who met me was friendly, warm, and professional but something went wrong with my finger-stick procedure. I was expecting a little prick like ones I've had in the past on my thumb, which don't hurt at all. Instead, when he pricked my middle finger it felt like someone had smashed it with a hammer. I told him this, that it REALLY hurt and he was very surprised but didn't seem to believe it. I actually got nauseous and it throbbed like hell. About 35 minutes after we left I decided to loosen the bandage because it was too tight. I was in the car with my son. As soon as I undid the Band-aid it immediately started bleeding again enough that we had to scramble to get some Kleenex and put a second Band-Aid on. It throbbed for hours that night. The next morning I visited my doctor and she saw that it was turning purple and said that should never happen. Based on that, I visited the Theranos website and sent a detailed email about my experience to [info@theranos.com](mailto:info@theranos.com). Later in the day I also sent pictures because by late afternoon the tip of my finger was purple and I couldn't even use it to grab things. No response. Now it has been almost two weeks and my doctor in Pacifica still hasn't received my lab results. The tip of my finger is actually STILL sore and it's two weeks tomorrow. The only

# Is the micro-sample a new and compelling standard?

- Limited documentation that fingersticks are actually predominant or preferred method.
- Lack of commitment to fingersticks in advertising to physicians office collections.
- Inherent limitations of finger sticks.
  - Sample storage and transport
  - Sample availability for repeat and sendout specimens.
  - Requirement for duplicate collections for failed sticks or tests requiring traditional samples

No new infrastructure needed.

You can draw samples in your office using your standard venipuncture draw method.  
Small specimens in your smallest collection containers are all we need.

# Does Theranos provide more rapid Turnaround time than traditional competitors?




## **Fast results. Fast answers.**

Our proprietary infrastructure allows us to perform our test analyses with unprecedented speed. So we can have results to you and your doctor in a matter of hours, not days. Which means a fast diagnosis to support better, more informed treatment.

Source: <https://theranos.com/our-technology>, 4/22/2015

# Does Theranos provide more rapid Turnaround time than traditional competitors?



Vince L.  
Cupertino, CA  
0 friends  
13 reviews

★★★★★ 1/22/2015

I hate needles and detest traditional blood draws. In my opinion, they extract way too much blood and the process belongs in the middle ages. I have hard-to-find veins which adds to the torture of the process. When a friend told me about the finger prick Theranos blood draw, I jumped at the opportunity to test this new company. My doctor wanted me to go to a traditional lab but I persisted and got his reluctant approval.

My experience with Theranos was excellent. I dropped into Walgreens in Palo Alto on a weekday at 12:30pm. I was the only one there for a blood draw. The sign-in at the Theranos counter was quick. All my 7 tests and panels qualified for the finger prick method (I had called their customer support to verify this beforehand). Theranos has their own waiting room and blood draw room. It was a relaxing environment. A large screen TV showed tropical fish swimming to the sound of soothing music. The technician explained the process, a heat pad was applied to my left hand and middle finger, and a device executed a painless prick to the tip of my middle finger. The technician gently squeezed my finger to extract a small amount of blood. The process was quick, painless, and much easier than a traditional blood draw.

A big bonus was that Theranos charged about a third what Quest and LabCorp had charged me for previous blood draws. Their prices are transparent and listed on their web site instead of being hidden. This really makes me wonder whether the traditional labs are engaged in price gouging.

I downloaded the Theranos iPad app and registered to get the results at the same time they were sent to my doctor. The blood test results showed up on the app 48 hours after the blood draw, faster than the traditional 3-4 days. I also received a copy of the official blood test results from Theranos in the mail two days later.

How important is turnaround time anyway?



# Does Theranos provide more rapid Turnaround time than traditional competitors?

- No published data on turnaround time.
- Anecdotal reports suggest 2-3 day turnaround times are typical, less than industry standard of 1 day.
- Central lab processing makes Turnaround times less than 1 day impossible or prohibitively expensive.
- True rapid turnaround time (0-4 hours) would require a totally different testing model, i.e. point of service devices in draw locations.

# Has Theranos changed standards for pricing and price transparency?



## covered and affordable.

Theranos is committed to making lab testing more accessible to everyone. That means pricing their tests at dramatically low rates. Theranos can accept major insurance carriers as well as Medicare and Medicaid. And if you're uninsured, they offer you the same discounted prices they offer everyone else. Because a test should cost the same, no matter who you are.

[Test menu](#)

# Has Theranos changed standards for pricing and price transparency?

A		
panel	ABO/RhD Blood Typing	\$4.10
82003	Acetaminophen	\$13.91
82024	ACTH (Adrenocorticotrophic Hormone)	\$26.55
87799	Adenovirus DNA, Quantitative	\$29.44
84460	Alanine Aminotransferase (ALT/SGPT)	\$3.64
82040	Albumin	\$3.40
84075	Alkaline Phosphatase (ALP)	\$3.56
82985	Alpha-1-Acid Glycoprotein	\$10.36
82103	Alpha-1-Antitrypsin, Total	\$9.24
82105	Alpha-Fetoprotein (AFP), Serum (Maternal)	\$11.53
82105	Alpha-Fetoprotein (AFP), Serum (Oncology)	\$11.53
82140	Ammonia	\$10.02
G0434	Amphetamines	\$10.00

## ABO/RhD Blood Typing

86900, 86901

Theranos price: \$4.10

Compare to Medicare price: \$8.20

### AT A GLANCE

TEST SAMPLE

THE TEST

COMMON QUESTIONS

### Formal name:

ABO/RhD Blood Typing

### Related tests:

Direct Antiglobulin Test; Indirect Antiglobulin Test; Compatibility Testing; Crossmatch, Antibody Identification; HLA Testing

### Why Get Tested?

To determine ABO blood group and Rh type

# Has Theranos changed standards for pricing and price transparency?



## Direct Pay Prices

Lab Test Price Comparison

CPT	Description	Medicare	AZ Medicaid	CA Medicaid	Theranos
80048	Basic Metabolite Panel	\$11.51	\$9.98	\$9.30	\$5.82
80055	Obstetric Panel	NA	22.57	37.99	30.07
80061	Lipid Panel	NA	15.80	13.88	9.21
82306	Vitamin D	40.29	27.33	24.79	20.35
83970	Parathyroid Hormone	56.17	48.71	45.39	28.36
84443	TSH	22.87	19.83	18.48	11.55
85025	CBC	10.58	7.57	8.55	5.35
85610	Prothrombin Time	5.35	4.65	4.32	2.70
87536	HIV-1 RNA Quantitative	115.80	100.42	93.57	58.48
86141	High-Sensitivity CRP	17.62	15.28	14.24	8.90

Source: Laboratory Economics from Arizona and California Medicaid programs and Theranos

Test Name	Current Procedural Terminology (CPT) Code**	Direct Pay Price at Time of Service
ALT	84460	\$16.00
Basic Metabolic Panel	80048	\$20.00
Bilirubin, Neonatal, Total & Direct	82248, 82247	\$25.00
Cardio IQ™ Lipoprotein Fractionation, Ion Mobility	83704	\$50.00
Complete Blood Count w/Differential and Platelet Count (CBC)	85025	\$20.00
Comprehensive Metabolic Panel	80053	\$29.00
Creatinine	82565	\$16.00
C-Reactive Protein (CRP)	86140	\$27.00
Estradiol	82670	\$90.00
Ferritin	82728	\$40.00
Glucose, Gestational Tolerance, 1 Hour	82950	\$16.00

# Has Theranos changed standards for pricing and price transparency?

- Theranos leads the industry in publishing clear accurate pricing.
- Theranos pricing conveys significant competitive advantage for self pay patients
- Theranos pricing *may* be attractive for patients with high co-pays or deductibles.
- Lack of insurance contracts may make Theranos model moot for insured patients required to use in network labs.
- **Unknown:** Will Theranos price schedules become the industry norm?

# Does the current operational model disrupt existing laboratory services?

1. Availability of draw station
  2. Utilization of finger sticks.
  3. Turnaround time.
  4. Price transparency.
  5. User experience.
1. Similar locations, expanded hours.
  2. No evidence of significant benefit or standard utilization
  3. Less than commercial competitors. Not meeting advertised claims.
  4. Pricing model attractive to self-pay patients and may impact industry pricing.
  5. Driving patient ordering and reporting.

# Does the current operational model disrupt existing laboratory services?

- Availability of draw stations? Similar to competitors, with longer hours.
- Utilization of finger sticks? No evidence of significant benefit or standard utilization.
- Turnaround time? Less than commercial competitors. Not meeting advertised claims.
- Price transparency? Pricing model attractive to self-pay patients and may impact industry pricing.
- User experience? Driving patient ordering and reporting.

# Is Theranos fundamentally changing the user experience?

## **A totally new experience.**

Over the next few months, we'll be introducing groundbreaking new spaces that transform the way you think about lab tests. Our Theranos Wellness Centers are designed to make your experience as easy and comfortable as possible. You can make an appointment or walk in at your leisure with your doctor's order form. Then enjoy our friendly new process. Everything is designed with your wellness in mind.

## **Unrivalled convenience.**

With Theranos, you can give your sample in your doctor's office, or bring your doctor's lab order to any of our convenient Theranos Wellness Centers. No more trekking to an out-of-the-way laboratory. No more dealing with your health on someone else's terms. With our extended hours – including nights and weekends – it's easy to fit your tests into your busy schedule.



# Is Theranos fundamentally changing the user experience?

Direct ordering of lab tests

Patient access to results

## Tech company Theranos pushes consumer lab-testing bill



Ken Alltucker, The Republic | [azcentral.com](http://azcentral.com)

9:58 p.m. MST February 27, 2015

**theranos**  
The blood test, reinvented.

Thousands of answers  
all in one tiny drop.



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Is the technology underlying  
Theranos clearly disruptive?

# Unique features of Theranos rise to prominence

Lack of peer reviewed publications

## Intensive serial biomarker profiling for the prediction of neutropenic fever in patients with hematologic malignancies undergoing chemotherapy: a pilot study

Steven M. Chan,<sup>1</sup> John Chadwick,<sup>2</sup>  
Daniel L. Young,<sup>3</sup> Elizabeth Holmes,<sup>3</sup>  
Jason Gotlib<sup>1</sup>

<sup>1</sup>Division of Hematology, Department of  
Medicine, Stanford University School of  
Medicine/Stanford Cancer Institute, CA,  
USA; <sup>2</sup>North Western Deansy, Three  
Piccadilly Place, Manchester, UK;

<sup>3</sup>Theranos Inc., Palo Alto, CA, USA

### Abstract

Neutropenic fever (NF) is a life-threatening complication of myelosuppressive chemotherapy in patients with hematologic malignancies and triggers the administration of broad-spectrum antimicrobials. The ability to accurately predict NF would permit initiation of antimicrobials earlier in the course of infection with the goal of decreasing morbid complications and progression to septic shock and death. Changes in the blood level of inflammatory biomarkers may precede the occurrence of NF. To identify potential biomarkers for the prediction of NF, we performed serial measurements of nine biomarkers [C-reactive protein (CRP), procalcitonin (PCT), interleukin (IL)-6, IL-8, IL-10, IL-1 $\beta$ , tumor necrosis factor- $\alpha$ , monocyte chemoattractant protein-1, and intercellular adhesion molecule-1] using a multiplex ELISA array platform every 6-8 hours in patients undergoing myelosuppressive chemotherapy for hematologic malignancies. We found that the blood levels of IL-6 and CRP increased significantly 24 to 48 hours prior to the onset of fever. In addition, we showed that frequent biomarker monitoring is feasible using a bedside micro sample test device. The results of this pilot study suggest that serial monitoring of IL-6 and CRP levels using a bedside device may be useful in the prediction of NF. Prospective studies involving a larger cohort of patients to validate this observation are warranted. This trial is registered at ClinicalTrials.gov (NCT01144795).

Hematology Reports 2014; volume 6:5466

# Unique features of Theranos rise to prominence

A large patent estate with broad  
claims

1	9,012,163	Modular point-of-care devices, systems, and uses thereof
2	8,984,932	Rapid measurement of formed blood component sedimentation rate from small sample volumes
3	D719,302	Finger warmer
4	8,883,518	Systems and methods of fluidic sample processing
5	8,862,750	Methods and systems for network connectivity
6	8,862,448	Integrated health data capture and analysis system
7	8,841,076	Systems and methods for conducting animal studies
8	8,840,838	Centrifuge configurations
9	8,822,167	Modular point-of-care devices, systems, and uses thereof
10	8,778,665	Detection and quantification of analytes in bodily fluids
11	8,741,230	Systems and methods of sample processing and fluid control in a fluidic system
12	8,697,377	Modular point-of-care devices, systems, and uses thereof
13	8,679,407	Systems and methods for improving medical treatments
14	8,669,047	Real-time detection of influenza virus
15	8,538,774	Methods and systems for assessing clinical outcomes
16	8,475,739	Systems and methods for fluid handling
17	8,470,524	Reducing optical interference in a fluidic device
18	8,435,738	Systems and methods for multi-analysis
19	8,392,585	Methods and systems for facilitating network connectivity
20	8,380,541	Systems and methods for collecting and transmitting assay results
21	8,283,155	Point-of-care fluidic systems and uses thereof
22	8,265,955	Methods and systems for assessing clinical outcomes
23	8,202,697	Medical device for analyte monitoring and drug delivery
24	8,158,430	Systems and methods of fluidic sample processing
25	8,101,402	Medical device for analyte monitoring and drug delivery
26	8,088,593	Modular point-of-care devices, systems, and uses thereof
27	8,012,744	Reducing optical interference in a fluidic device
28	8,008,034	Reducing optical interference in a fluidic device
29	8,007,999	Real-time detection of influenza virus
30	7,888,125	Calibration of fluidic devices
31	7,824,612	Bodily fluid analyzer, and system including same and method for programming same
32	7,635,594	Point-of-care fluidic systems and uses thereof
33	7,291,497	Medical device for analyte monitoring and drug delivery

A subset of patents describes methods, systems and devices for analyzing broad categories of samples.

**United States Patent**  
**Holmes**

**8,435,738**  
**May 7, 2013**

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Systems and methods for multi-analysis

### **Abstract**

Systems and methods are provided for sample processing. A device may be provided, capable of receiving the sample, and performing one or more of a sample preparation, sample assay, and detection step. The device may be capable of performing multiple assays. The device may comprise one or more modules that may be capable of performing one or more of a sample preparation, sample assay, and detection step. The device may be capable of performing the steps using a small volume of sample.

# A smaller subset of patents describes methods, systems and devices for measurement of specific analytes

United States Patent  
Dayel , et al.

8,984,932  
March 24, 2015

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Rapid measurement of formed blood component sedimentation rate from small sample volumes

## Abstract

Devices and methods are described for measuring formed blood component sedimentation rate. Some of the methods may use (1) centrifugal techniques for separating red blood cells from plasma and (2) video and/or still imaging capability. Both may be used alone or in combination to accelerate formed blood component sedimentation and to measure its rate. In one example, the method may advantageously enable rapid measurement of sedimentation rate using small blood sample volumes. Automated image analysis can be used to determine both sedimentation rate and hematocrit. Automated techniques may be used to compensate for effects of hematocrit on uncorrected sedimentation rate data.

# Most of the patents submitted are unrelated to the current Theranos business model

- Point of care devices
- Wearable and ingestable devices
- Systems for data analysis, transmission and decision making.

# Unique features of the Theranos rise to prominence

Intense secrecy regarding technical operations

+You Search Images Maps Play YouTube News Gmail More +

Google theranos and secrecy

Web Images Videos News Shopping Maps Books

About 5,420 results

**Any time**  
Past hour  
Past 24 hours  
Past week  
Past month  
Past year

**All results**  
Verbatim

[One Woman's Drive to Revolutionize Medical Testing - The New ...](#)  
www.newyorker.com/magazine/2014/12/15/blood-simpler ▾  
15 Dec 2014 ... Some observers are troubled by Theranos's secrecy; its blood tests may well turn out to be groundbreaking, but the company has published ...

[The New Yorker on the promise, the secrecy and the challenges of ...](#)  
medcitynews.com/.../new-yorker-promise-secrecy-challenges-super-startup-theranos/ ▾  
8 Dec 2014 ... It also brings up the discrepancy between health and high tech, and how the secrecy that shrouds Theranos – and Holmes – might not be as ...

[Theranos - Wikipedia, the free encyclopedia](#)  
en.wikipedia.org/wiki/Theranos ▾  
Theranos is a privately held health technology and medical laboratory ... suit in court in Santa Clara accusing former employees of breaching company secrecy.

[Finally, Some Important New Details about the Theranos Business ...](#)  
labsoftnews.typepad.com/.../finally-some-important-details-about-theranos. html ▾  
15 Dec 2014 ... Some observers are troubled by Theranos's secrecy; ...the company has published little data in peer-reviewed journals describing how its ...

[New Yorker: Theranos founder's description of chemistry process ...](#)  
pathologyblawg.com/.../new-yorker-theranos-founders-description-chemistry-process-comically-vague/ ▾  
17 Dec 2014 ... Theranos shrouds itself in secrecy and will not divulge the proprietary methods by which it obtains its diagnostic results from a mere drop of ...



February 17, 2015, Vol 313, No. 7 >

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Viewpoint | February 17, 2015

## Stealth Research Is Biomedical Innovation Happening Outside the Peer- Reviewed Literature?

John P. A. Ioannidis, MD, DSc<sup>1</sup>

[+] Author Affiliations

JAMA. 2015;313(7):663-664. doi:10.1001/jama.2014.17662.

Text Size: A A A

Article

References

Information about Theranos, a privately held biotechnology company that has developed novel approaches for laboratory diagnostic testing, has appeared in *The Wall Street Journal*, *Business Insider*, *San Francisco Business Times*, *Fortune*, *Forbes*, *Medscape*, and *Silicon Valley Business Journal*—but not in the peer-reviewed biomedical literature. As of January 5, 2015, a search in PubMed using *Theranos* as a search term identified affiliations for only 2 unrelated articles coauthored by Theranos Inc employees, although these 2 reports do not offer insights about their company.

Conversely, according to the non–peer-reviewed sources mentioned above, Theranos is “revolutionizing the blood test” and this “is a golden idea”: “the company can run hundreds of tests on a drop of blood far more quickly than could be done with whole vials in the past—and it costs a lot less.”<sup>1</sup> The company is estimated to be worth \$9 billion.<sup>2</sup> Test results are “near-instantaneous.”<sup>3</sup>

Moreover, the company has teamed with Walgreens pharmacies in Palo Alto and Arizona to create “Theranos Wellness Centers.” A footnote in the respective Walgreens webpage<sup>4</sup> mentions that the laboratories are Clinical Laboratory Improvement Act–certified. According to the same sources, Theranos has operated in stealth mode for more than a decade, not publishing anything in the literature while preparing to change the entire health system: “One closely guarded secret is... how exactly the technology behind its blood test works.”<sup>1</sup>

# Publication of key findings adds value to new companies

Results to Date: December 6, 2013



## Invitae Analytic Validation Summary

### Executive Summary

Analytic validity of the Invitae genetic test has been demonstrated in three studies: Two of these studies utilize well-known reference samples and examine a broad set of genes and broad classes of DNA variation. A third study utilizes clinical samples from two major academic medical centers and focuses on BRCA1 and BRCA2. In all cases, independent data on these individuals from traditional diagnostic technologies (such as Sanger sequencing) is available as a "gold standard" for comparison.

Results from 712 individuals tested to date in these three studies are summarized in this document. **Over this combined set, in direct comparison with the "gold-**

**standard" data, 100% analytic sensitivity and 100% analytic specificity has been observed for all pathogenic DNA variations within the analytic range of the Invitae test.** Both small sequence changes as well as larger deletion/duplication events are included in this result. We note that this level of sensitivity and specificity was achieved from the primary sequencing data alone without either gap-filling or confirmation of pathogenic variants using an orthogonal technology. Nevertheless, Invitae's current standard testing procedures utilize both gap-filling and confirmation on patient samples to further ensure completeness and accuracy.

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& NEONATAL  
MEDICINE

<http://informahealthcare.com/jmf>  
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J Matern Fetal Neonatal Med, 2013; 26(12): 1180-1185  
© 2013 Informa UK Ltd. DOI: 10.3109/14767058.2013.770464

informa  
healthcare

## Clinical utility and cost of non-invasive prenatal testing with cfDNA analysis in high-risk women based on a US population

Ken Song<sup>1</sup>, Thomas J. Musci<sup>1</sup>, and Aaron B. Caughey<sup>2</sup>

<sup>1</sup>Ariosa Diagnostics, Inc., San Jose, CA, USA and <sup>2</sup>Oregon Health & Science University, Portland, OR, USA

Genetics  
in Medicine

ORIGINAL RESEARCH ARTICLE

©American College of Medical Genetics and Genomics  
**Open**

## An empirical estimate of carrier frequencies for 400+ causal Mendelian variants: results from an ethnically diverse clinical sample of 23,453 individuals

Gabriel A. Lazarin, MS<sup>1</sup>, Imran S. Haque, PhD<sup>1</sup>, Shivanl Nazareth, MS<sup>1</sup>, Kevin Iori, BS<sup>1</sup>, A. Scott Patterson, MA<sup>1</sup>, Jessica L. Jacobson, MD<sup>1,2</sup>, John R. Marshall, MD<sup>1,3</sup>, William K. Seltzer, PhD, FACMG<sup>1</sup>, Pasquale Patrizio, MD<sup>4</sup>, Eric A. Evans, PhD<sup>1</sup> and Balaji S. Srinivasan, PhD<sup>1,5,6</sup>

**Purpose:** Recent developments in genomics have led to expanded carrier screening panels capable of assessing hundreds of causal mutations for genetic disease. This new technology enables simultaneous measurement of carrier frequencies for many diseases. As the resultant rank-ordering of carrier frequencies impacts the design and prioritization of screening programs, the accuracy of this ranking is a public health concern.

**Methods:** A total of 23,453 individuals from many obstetric, genetics, and infertility clinics were referred for routine recessive disease carrier screening. Multiplex carrier screening was performed and results were aggregated for this study.

**Results:** Twenty-four percent of individuals were identified as carriers for at least one of 108 disorders, and 5.2% were carriers for

multiple disorders. We report tabulations of carrier frequency by self-identified ethnicity and disease.

**Conclusion:** To our knowledge, this study of a large, ethnically diverse clinical sample provides the most accurate measurements to date of carrier frequencies for hundreds of recessive alleles. The study also yields information on the clinical considerations associated with routine use of expanded panels and provides support for a pan-ethnic screening paradigm that minimizes the use of "racial" categories by the physician, as recommended by recent guidelines.

*Genet Med* 2013;15(3):178-186

**Key Words:** carrier frequency; carrier screening; genetic testing; pan-ethnic; recessive disease

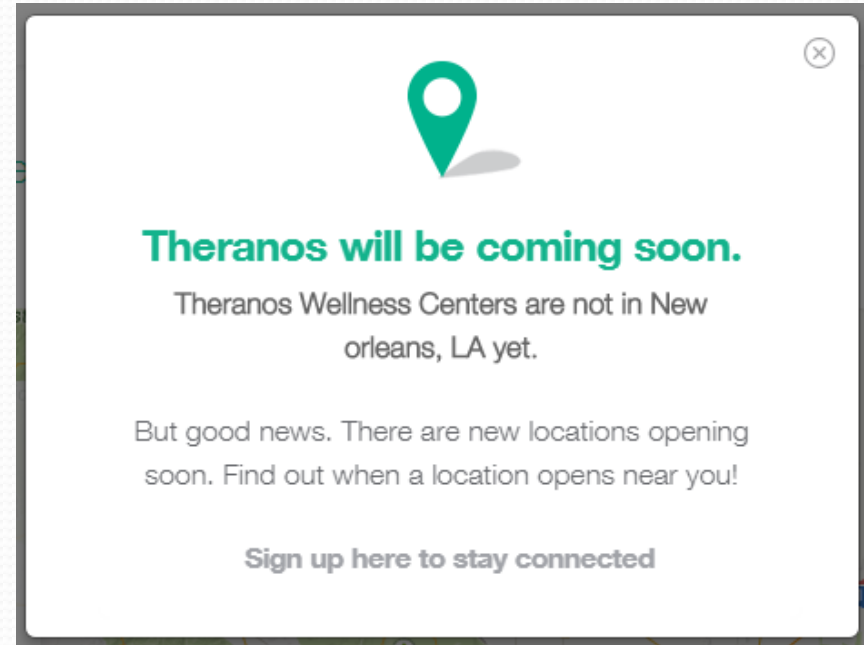
Where does Theranos go  
from here?

# Where Does Theranos go from here?

- Expansion of current model.
- Patient directed testing
- Point of service diagnostics using current Walgreens distribution.
- Growth of true point of care and wearable technologies.
- FDA oversight

# Expansion of the current model

- Stated goal is presence in all 50 states in “substantial” portion of 8200 Walgreens locations
- Limited growth on the Arizona footprint
  - Expansion from 20-40 sites in last year confined to Phoenix Metro area.
  - Phoenix area CLIA lab built to service Arizonaz locally.
  - Large Newark CA area CLIA lab.



# Limits to Expansion of the Model

- Difficulty to compete for routine laboratory business nationally with a small number of CLIA sites because of the cost and time limitations of sample transport.
- Development of regional CLIA sites would require each site to validate each assay as an LDT.
- Potentially prohibitive cost of logistics for low cost, low margin samples.
- Potentially prohibitive cost of dedicated low productivity phlebotomy staff.
- Absolute necessity to develop ability to take all clinical tests done needed by a patient. Will Cleveland clinic become their partner to provide reference lab backup for tests they can do themselves.

# Growth Potential of Patient Directed ordering

- Theranos presumably believes this is significant growth area.
- How large is the dollar value of patient directed ordering?
  - Low cost tests (cholesterol, INR, HbA1C, cholesterol)
  - No insurance coverage.
  - Variable state regulations.
- Competition from (reluctant) competitors
- Competition from direct to consumer waived tests.

# Evolution of the current model to testing performed on site at Walgreens

- 4 hour turnaround time can only be provided doing on site testing.
- Much of patent estate is geared to “point of care” technologies.
- Would satisfy needs of impulse based consumers.



# FDA obstacles to migration of current model

- Manufacture of Point of service devices would require FDA approvals either as In Vitro Diagnostics, or as “waived” tests.
  - Use of devices as Theranos devices as IVD’s would require licensure of every site as a laboratory.
  - Use of devices as “waived tests” would require appropriate licensure and oversight of testing personnel.
- Approval for essentially all tests would have to be in place before putting devices into use.

# Development of ingestable and wearable devices and communications technologies

- A major point of focus in Theranos patents
- Would require different pathways of FDA approval, regulatory oversight, ordering and billing.
- A highly competitive field

Companies Developing Non-invasive and Wearable Glucose Monitoring Devices That Can Report Test Data in Real Time to Physicians and Clinical Laboratories

Category: [Instruments & Equipment](#), [Laboratory](#)



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34



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17



+1

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Share

19

[Instruments & Laboratory Equipment](#), [Laboratory Management and Operations](#), [Laboratory News](#), [Laboratory Pathology](#), [Management & Operations](#)

Published: October 17 2014

*Goal is to shift glucose testing away from medical laboratories and make it easier for diabetics to do their own testing, while capturing glucose test results in patient records*



# Has Theronos revolutionized the industry?

Promotion versus reality

# Has Theranos Revolutionized the Industry?

- |  |            |
|--|------------|
| • Central lab instrumentation                  | No         |
| • Point of care instrumentation                | Not yet    |
| • Use of microtainers                          | Not proven |
| • Price transparency and low pricing           | Yes        |
| • Patient empowerment                          | Maybe      |
| • Self pay provision of services               | Yes        |
| • Order entry/Results reporting/EMR interfaces | No         |

# Posttest

1. With regard to my knowledge of the Theranos business model, I consider myself
  - A. Very familiar
  - B. Somewhat familiar
  - C. Slightly familiar
  - D. Not at all familiar
2. I view the threat of Theranos to my business to be
  - A. Very significant
  - B. Somewhat significant
  - C. Slightly significant
  - D. I do not view Theranos as a threat.

# Silicon valley and Innovation in Laboratory Medicine

Natural Partners

# Silicon Valley meets Laboratory Medicine

## Necessary inputs

- Clinical and Medical Expertise.
- IT expertise
- Engineering Expertise
- Skilled Technical Workforce
- Access to Venture Capital

## Successful Ventures

- Ariosa
- Invitae
- Counsyl

# What to look for in a groundbreaking venture?

- Clear aims and understanding of target market
- Desire to capture major share of the market
- Pricing transparency
- Reduced cost compared with competitors
- Use of Social Media
- Bypass traditional “key opinion leaders”
- Success marked by readily apparent rapid growth



# What to look for in a groundbreaking venture?

- ~~• Clear aims and understanding of target market~~
- Desire to capture major share of the market
- Pricing transparency
- Reduced cost compared with competitors
- Use of Social Media
- Bypass traditional “key opinion leaders”
- ~~• Success marked by readily apparent rapid growth~~
- *Failure to leverage the unique advantages of their Walgreen partner!!*

In Conclusion:

Theranos has shown some of the attributes of successful companies

- Talented and visionary management
  - Access to Capital
  - Management of the Media
  - Technological sophistication
- 
- *But this may not be enough*

# Questions? Comments?

Thank you