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Direct-to-Consumer Testing: The Business with Lifestyle Tests

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Potential conflict of interest

DGKL (section laboratory managent)
BDL (section hospital laboratories)
IFCC: C-CLM
EFLM: TFG-TE

KJ Lackner, Gillery P et al. The Theranos phenomenon, scientific transparency and freedom of speech
Clinical Chemistry and Laboratory Medicine (CCLM) 2016 54: 1403–5
DOI: 10.1515/cclm-2016-0520

Objectives

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- detail many forms of DTCT and how these tests should be considered within the realm of what we traditionally consider POCT
- experiences with DTCT in Germany as opposed to the US
- describe differences between clinical pathology labs (healthcare) and non-healthcare lab testing services
- challenges of DTCT with the Genetics Diagnostics Act, goals of the law (inaccurate promises, discrimination, data protection)

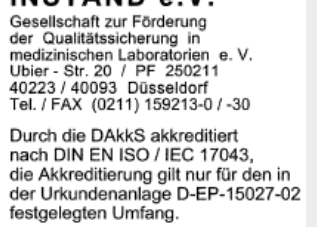
"The best way to find out if you can trust somebody is to trust them."

Ernest Hemingway

Trust

Höchste Qualität und Sicherheit.

humatrix hat schon immer Maßstäbe gesetzt: durch maximale Automatisierung im Labor, als erster Anbieter in Apotheken, mit dem einzigartigen Safekit und als langjähriger Partner der großen TV-Sender. Und so können Sie sich auch in Punkto Qualität und Sicherheit absolut auf uns verlassen.



FDA
clinical validity (accuracy with which test identifies, measures, or predicts presence or absence of a clinical condition or predisposition in a patient)

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CLIA
safety and effectiveness of test system does not address clinical validity of any test

J Lab Med 2015; 39(1): 26–69 DE GRUYTER

On 19 September 2014, the current version of the "Guideline of the German Medical Association on Quality Assurance in Medical Laboratory Examinations" was published. It featured an introduction by the German Medical Association.

Revision of the "Guideline of the German Medical Association on Quality Assurance in Medical Laboratory Examinations – Rili-BAEK"

Practical Implications of the German Genetic Diagnostics Act (GenDG) for Laboratory Medicine, the Human Genetics Laboratory and for Genetic Counseling
J Lab Med 2011(35) 243–53, DOI: 10.1515/JLM.2011.045

Rilibäk

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5.2 Personnel

Medical laboratory examinations must only be performed by personnel who are professionally qualified corresponding to legal regulations, and who are authorised by management.

The number of personnel must be sufficient with regard to the amount of work.

6.2 Procedures for conducting medical laboratory examinations

6.2.1 The medical laboratory may only use examinations procedures that meet medical requirements.

6.2.2 The medical laboratory may only use validated examinations procedures. It has to document the procedure used for validation and the results obtained.

Restricted activities § 9 (MTA-Gesetz - MTAG)

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In healthcare, following activities are restricted to persons with a permission ..

testing in morphologic Hematology, Immunohematology, Hemostaseology, Clinical Chemistry, Microbiology, Parasitology and Immunology including reporting, quality control and technical validation

Reichsgesetzblatt 251

Teil I

1939	Ausgegeben zu Berlin, den 20. Februar 1939	Nr. 30

Tag	Inhalt	Seite
17. 2. 39	Gesetz über die berufsmäßige Ausübung der Heilkunde ohne Bestallung (Heilpraktikergesetz)	251
17. 2. 39	Gesetz über die Besoldung der Hochschullehrer (Vierunddreißigste Ergänzung des Besoldungsgesetzes)	252

§ 10 § 9 does not apply to
1. physicians, dentists and naturopathics/non-medical practitioners/quacksalvers,
2. Medical laboratory technician students, 5. medical laboratory technicians,
6. Other medical licensed person under direct supervision and responsibility by a person under #1

Challenges by DTC/DAT

no quality criteria at all have to be followed if laboratory tests are performed by non-health care professionals allowing a free movement of services under the consumer rights directive 2011/83/EU

Orth, M. and P. Luppa (2014). Dtsch Arztebl 2015; 112(5): A-174

The Directive on Consumer Rights aims at achieving a real business-to-consumer (B2C) internal market, striking the right balance between a ***high level of consumer protection*** *and the* ***competitiveness of enterprises****.*

laboratory = a facility that performs certain testing on human specimens in order to obtain information that can be used for the diagnosis, prevention, or treatment of any disease or impairment of a human being

CLIA regulations and standards do not differentiate between facilities performing DAT and facilities performing provider ordered testing. All facilities must obtain CLIA certificate prior to conducting patient testing, *including* DTC/DAT

Evidence based medicine

Healthcare

Lifestyle

Lab Tests

POCT

DTCT

Animal testing, food testing

Commercial lab testing

Foodstuff IgG_4

Evidence based medicine

Healthcare

Continuous glucose monitoring

Lab Tests

Lifestyle

POC

Commercial lab testing

DTCT

Animal testing, food testing

Healthcare -- „Medical Act“

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- Restriction of healthcare (=diagnosing illnesses, prescribing diagnostic examinations, using invasive/risky diagnostic techniques, determining medical treatment, prescribing medications, clinical monitoring of patients with problematic health, pregnancy care and deliveries, isolation measures) to physicians
- *Prohibition of (exclusive) telemedicine*
- *Critical: (external) IT service provider essential in medical process*
- *Physician may not extend services by hiring employees unlike a commercial firm*
- *Restrictions in advertising and access to tests (GenDG)*

primum non nocere, secundum cavere, tertium sanare

Follow up costs

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An Unwelcome Side Effect of Direct-to-Consumer Personal Genome Testing

Raiding the Medical Commons

Amy L. McGuire, JD, PhD
Wylie Burke, MD, PhD

IT IS NOW POSSIBLE FOR INDIVIDUALS TO LEARN ABOUT their genetic susceptibility to dozens of common and complex disorders, such as coronary artery disease, diabetes, obesity, prostate cancer, and Alzheimer disease, without ever seeing a physician. Direct-to-consumer personal genome testing companies hope to empower consumers to take control of their health by providing tailored assessments of genetic risk based on reported associations between genomic variation and susceptibility to disease.

Several states limit or forbid this practice as a violation of state law that requires the appropriate involvement of a licensed physician when providing medical diagnostic information.[1] Personal genome testing companies claim that their services are for informational and educational purposes only. They warn consumers that the information should not be used for diagnosis, treatment, or health ascertainment purposes and direct them to their physicians if they have questions or concerns about their health status.[2,3] sel patients accordingly. Physicians are also accustomed to talking with patients about health information disclosed on the Internet or through other media outlets. At the same time, primary care physicians have limited time with patients, face many competing demands,[3] and are poorly reimbursed for time spent counseling patients about preventive care. Patient concerns about direct-to-consumer test results have the potential to exacerbate these problems and strain already limited health care resources.

Raiding the Medical Commons

The clinical value, if any, of most direct-to-consumer personal genome tests remains unproven. A statistically significant association between a particular genomic variant and a disease does not necessarily mean that the presence of that variant in a given individual is clinically meaningful. Many of the variants discovered in genome-wide association studies are associated with only marginal increases in risk, with odds ratios often 1.5 or less.[4] The usefulness of this information for clinical decision making is unclear.

Although physicians need to be prepared for patient inquiries about personal genome test results and arguably have

JAMA, December 10, 2008—Vol 300, No. 22 2669

Hiatt, H. H. (1975). "Protecting the medical commons: who is responsible?" N Engl J Med **293(5): 235-41.**

NATURE | COMMENT

Research integrity: Don't let transparency damage science

Stephan Lewandowsky & Dorothy Bishop

25 January 2016

Stephan Lewandowsky and Dorothy Bishop explain how the research community should protect its members from harassment, while encouraging the openness that has become essential to science.

- Blogs and social media enable rapid correction of science by scientists (see Nature http://doi.org/fx24wg; 2012).
- **Yet social media and online comments also offer an easy way to inject biased, incorrect or misleading information. And because engagement with critics is a core element of scientific practice, researchers may feel obliged to respond even to 'trolls' (online harassers).**

Nature 529, 459–461 (2016) doi:10.1038/529459a

Bad Blood: Secrets and Lies

THERANOS

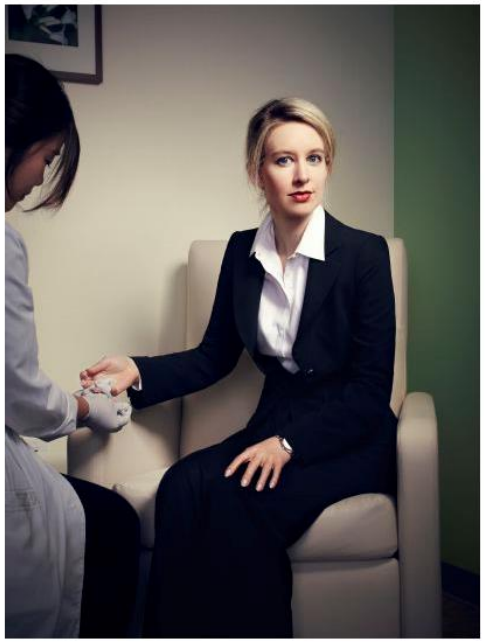
This CEO is out for blood

by Roger Parloff @rparloff JUNE 12, 2014, 7:37 AM EST

Elizabeth Holmes founded her revolutionary blood diagnostics company, Theranos, when she was 19. It's now worth more than $9 billion, and poised to change health care.

In the fall of 2003, Elizabeth Holmes, a 19-year-old sophomore at Stanford, plopped herself down in the office of her chemical engineering professor, Channing Robertson, and said, "Let's start a company."

Robertson, who had seen thousands of undergraduates over his 33-year teaching career, had known Holmes just more than a year. "I knew she was different," Robertson told me in an interview. "The novelty of how she would view a complex technical problem–it was unique in my experience."



Theranos founder and CEO Elizabeth Holmes

Photograph by Joe Pugliese for Fortune

Left, by Fred Duval/FilmMagic; Right, by Michael Kovac, both from Getty Images.

"They basically tell the story of how Elizabeth Holmes created these fraudulent blood-testing machines, raised $9 billion through venture capitalists in Silicon Valley, and refuses to admit they don't work even when it is obvious the testing is inaccurate. They employ a big-time litigator and threaten to sue anyone who challenges her."

http://www.inquisitr.com/3242822/jennifer-lawrence-no-bad-blood-as-theranos-film-finds-a-buyer-thanks-to-talent-behind-pitch/#DLm3KA2SQevcl5D5.99

Diamandis, E. & Plebani, M. (2016) *Clinical Chemistry and Laboratory Medicine (CCLM)*, 54,e313-4

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Theranos Inc

Feb 13, 2016
Theranos Files Plan to CMS for Fixing California Lab Problems

Feb 5, 2016
Theranos Gets Additional Week to Respond to U.S. Inspection

Jan 29, 2016
Theranos Is Running Out of Time

Partnership with

- Cleveland Clinic to decrease the cost of lab tests

Cleveland Clinic

- Pennsylvania insurers
- AmeriHealth Caritas
- Capital BlueCross

Jan 29, 2016
Walgreens Suspends Theranos California Lab After U.S. Report

Jan 28, 2016
Theranos Lab Faults Jeopardized Patient Health, U.S. Says

Nov 11, 2015
23andMe CEO Says She Won't Sell After DNA Test Firm's Comeback

Oct 28, 2015
Flipboard's Fanfare Fades as Executives Exit, Sale Talks Stall

Oct 27, 2015
Theranos Device Validation Is Flawed, FDA Inspection Finds

Oct 21, 2015
Theranos CEO Defends Blood Testing Company at Conference

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Wellness FX

Included Tests

Advanced Cholesterol

Our advanced cardiovascular and lipid panels go beyond typical cholesterol testing to uncover risk factors for early heart disease.

Total Cholesterol | HDL | LDL | Triglycerides | Lp(a) | ApoB

Basic Inflammation

Research has shown that the high sensitivity C-reactive protein (hs-CRP) inflammation marker is associated with the potential onset of diseases such as cancer, dementia, cardiovascular disease, and many other chronic diseases.

hs-CRP

Thyroid & Blood Sugar

Blood sugar (measured by glucose testing) and HbA1c (average blood sugar) are the primary indicators for diabetes. The thyroid significantly influences metabolism and energy use, and is the most common hormone imbalance in the U.S.

TSH | Glucose | HbA1c

Liver & Kidney Health

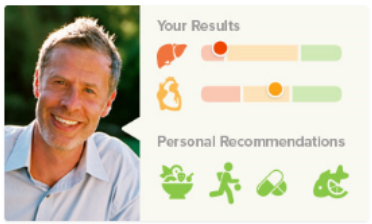
Your kidney and liver detoxify your body of harmful pollutants from your everyday environment. Poor liver and kidney health can lead to chronic disease, unwanted weight gain, loss of energy and more.

BUN/Creatinine | AST & ALT | Total Bilirubin | Albumin | Total Protein

Basic Nutrients

The right balance of electrolytes helps optimize nerve and cellular functions that support nearly every system in the body. Calcium and vitamin D are essential for strong, healthy bones, strengthening the immune system, and reducing the risk of long-term chronic diseases.

25-Hydroxy Vitamin D | Calcium | Electrolytes | Bicarbonate



Adding Personalized Consultations

Schedule a one-on-one telephone consultation with a WellnessFX specialist based on your unique diet, exercise, and lifestyle goals. From women's health to endurance training to weight loss, our practitioners will help you identify potential health risks or areas of improvement. Get answers on how to improve, not just prevent, on your time, from the comfort of your own home.

Browse practitioners in your state

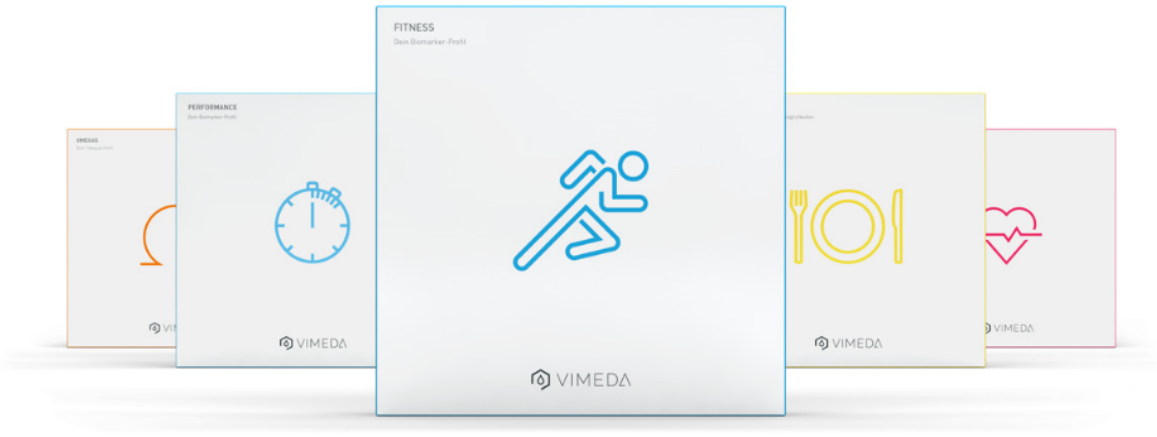
Buy Baseline $198 Add to Cart

The best ist within you Dir

Personalisiertes Health Coaching mit den Vimeda Tests

FITNESS · PERFORMANCE · NUTRITION · VITAMIN D · OMEGAS · PREMIUM · AGE VITALITY · BASIC

Vimeda.de



- Blood test for at home
- From few drops of blood
- Easy and time-saving
- Certified labs
- Results easy to unterstand
- Individual recommendations

Intended purpose / Disclaimer Vimeda.de

Zweckbestimmung Medizinprodukt

Die Vimeda-Plattform ist eine onlinebasierte medizinische Anwendung, die dem Kunden die Möglichkeit gibt, selbst abgenommene Bluttests ohne venöse Punktion auszuwerten und ein Feedback über verschiedene Blutparameter (auch Biomarker genannt) zu erhalten. Die für die Plattform notwendigen Proben werden per Post einem spezialisiertem Labor zugesandt, analysiert und das Ergebnis auf der Vimeda-Plattform unter der URL: www.vimeda.de dem Kunden präsentiert. Dort erhält der Kunde neben der Visualisierung seiner labordiagnostischen Blutparameter zudem allgemeingültige Handlungsempfehlungen zu den einzelnen Blutparametern. Die Auswertungen und Handlungsempfehlungen können auch einem Arzt als weitere medizinische Information für weiterführende Diagnostiken und Therapien zur Verfügung gestellt werden.
Die Vimeda-Plattform kann eine professionelle medizinische Beratung oder Behandlung durch einen approbierten Arzt oder eine professionelle Ernährungsberatung unterstützen, aber in keinem Fall ersetzen. Vimeda verweist auf der Plattform für den Kunden gut sichtbar und explizit darauf, dass die Dienstleistungen lediglich eine Ergänzung darstellen.

CE

Unsere Partner und Zertifizierungen

Sichere und schnelle Test-Kits für zuhause

Einfache und schnelle Durchführung mit Videoanleitung - jederzeit und überall.

So funktionieren die Tests ›

Zuverlässige Laborergebnisse

Standardisiertes Testverfahren durch unser zertifiziertes Labor.

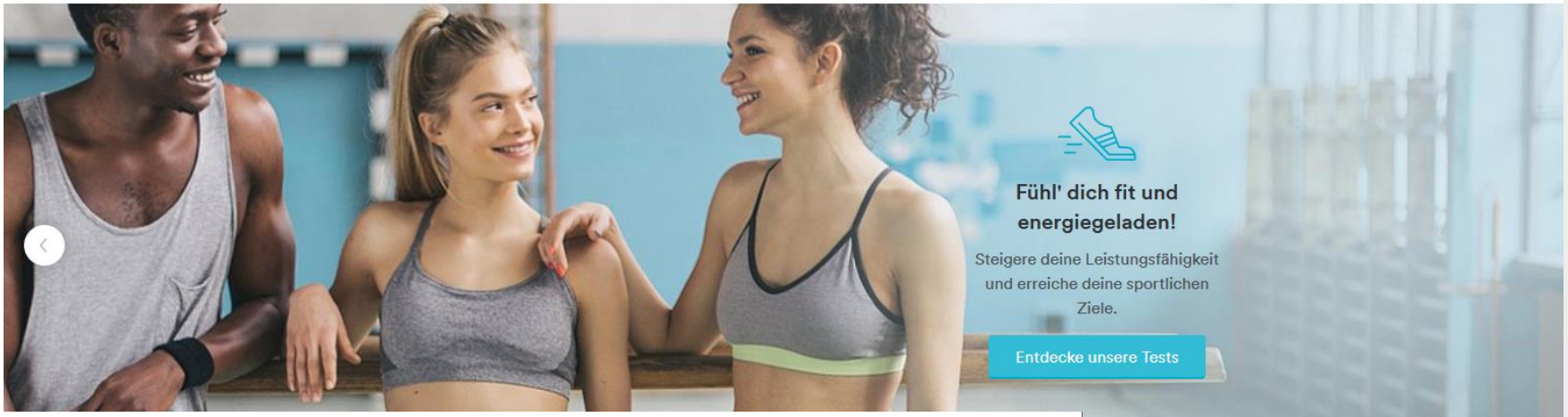
Unser Labor ›

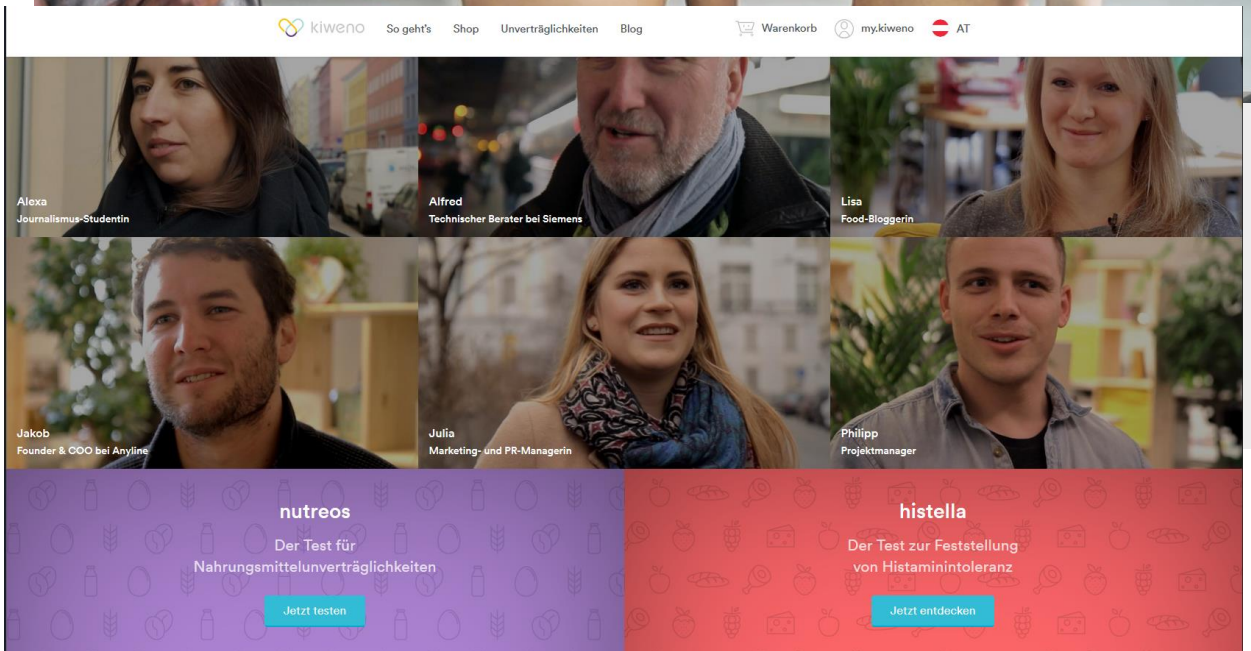
Alle Ergebnisse online - intuitiv aufbereitet

Testergebnisse, Gesundheitsempfehlungen und Tipps für deine Ernährung - alles aus einer Hand.

Mehr zu my.kiweno ›

IgG_4 against foodstuff





kiweno.de

Obligation to render qualified services and in person

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In Germany
Common service law: „In case of doubt, services have to be performed in person by the party/person obliged to render the service (§ 613 (1) BGB)“

Physician law: §19 (1) rules of professional conduct

public insurance: § 32 (1) „Zulassungsverordnung für Vertragsärzte“ and § 15 (1) „Bundesmantelvertrag-Ärzte“

Medicine is not an exact science, and at times requires some educated guesswork on the part of physicians and laboratories, Gary Marchant, a law professor at Arizona State University, told BuzzFeed. “Every time they’re wrong, it doesn’t mean there should be a lawsuit…But on the other hand, when they clearly haven’t lived up to ***professional*** *expectations, there should be. There’s a gray zone, that’s a difficult line to draw.”*

A Lawsuit’s Potential Impact on Genetic Test Reporting

Case involving misdiagnosis of a genetic variant illuminates inadequacies in genetic testing lab standards.

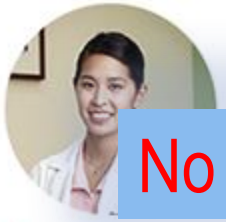
Date: MAY.5.2016 // **Source:** CLN Stat

It's easy to get started

1.
Get a lab order from your clinician.

2.
Visit your nearest Theranos™ Wellness Center inside Walgreens.

3.
Bring your lab order to the pharmacy.



4.
Our friendly technician will take your sample.

No need for FDA approval ?

The goal is to make blood testing simple and acc
fast, even publishing fees for its tests online to m
transparent as possible and empower the consu

Just show up with an ID, insurance card and a d
Walgreens pharmacist will draw your blood on th
Theranos lab. The goal is to protect the integrity
the customer's data.

There's a Theranos app, and results are typically
within 24 hours. "A typical lab test for cholesterol
a recent *New Yorker* profile of Holmes commen
at Walgreens costs $2.99."

Theranos has been able to keep its technology under wraps as it differs from other diagnostic labs, including Quest and Laboratory Corporation of America, that rely on equipment from outside manufacturers like Siemens and Roche Diagnostics.

While those manufacturers requires FDA approval, Theranos does not because it makes its own equipment and doesn't sell it or move it out of its labs.

Theranos is currently certified in 48 states, with two more applications pending, under the federal Clinical Laboratory Improvement Amendments of 1988

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Offering greater accessibility to blood tests, virtual painless testing, and a much lower cost, Holmes' invention helps patients get tested earlier and more frequently. In one example, a women with diabetes **reduced the costs … of tests she required from € 711 using traditional blood analysis methods down to € 28** using Holmes's technology

Point-of-care (POC) devices used by Theranos phlebotomists – technicians licensed to take blood – draw blood virtually painlessly through a trigger tap on the subject's finger. … The more sophisticated tests require at the very most no more than a drop of blood (around 100 µl). But new technologies developed by the company are pushing this down to the 1 to 3 µl level ...

The technology can work on tiny samples due to the application of two methods: dilution and detectors. When a sample is diluted, it is possible to detect signals from multiple substances present in the sample in widely varying concentrations. This enables a more complex analysis …

Testing fees THERANOS - DE (private) - DE (public)

				EBM	GOÄ
☐	Alanine Aminotransferase (ALT)	84460	$3.64	€0.22	€2.33
☐	Amylase	82150	$4.46	€0.36	€2.99
☐	Antinuclear Antibodies, Screen (ANA)	86038	$8.31	€6.57	€29.73
☐	Aspartate Aminotransferase (AST)	84450	$3.56	€0.22	€2.33
☐	Calcium	82310	$3.55	€0.22	€2.33
☐	Cholesterol	82465	$2.99	€0.22	€2.33
☐	Cortisol, Total	82533	$11.21	€5.58	€14.57
☐	C-Reactive Protein (CRP)	86140	$3.56	€1.04	€5.83
☐	C-Reactive Protein, High Sensitivity (hsCRP) ◇	86141	$8.90	€4.41	€11.66
☐	Creatine Kinase	82550	$4.48	€0.22	€2.33
☐	Estradiol	82670	$19.21	€4.14	€20.40
☐	Follicle Stimulating Hormone (FSH)	83001	$12.77	€4.05	€20.40
☐	Luteinizing Hormone (LH)	83002	$12.73	€4.05	€20.40
☐	Progesterone	84144	$14.34	€3.42	€20.40
☐	DHEA-S	82627	$15.28	€6.21	€20.40
☐	Prolactin	84146	$13.32	€4.14	€20.40
☐	Testosterone, Free	84402	$17.50	€2.25	€20.40
☐	Testosterone, Total	84403	$17.75	€2.25	€20.40

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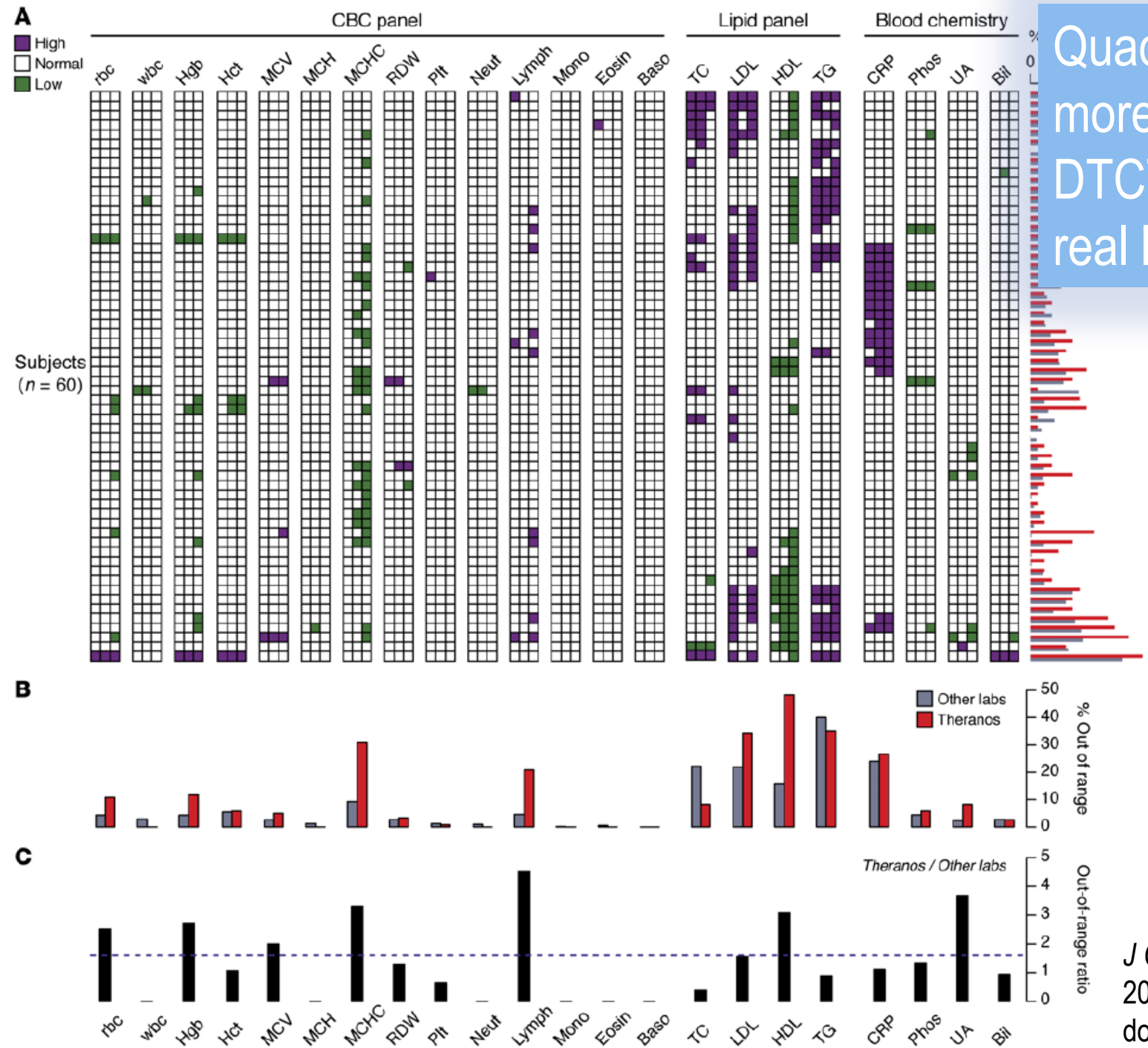

Quadruple times more outliers in DTCT than in real lab tests

J Clin Invest.
2016;126:1734–44
doi:10.1172/JCI86318.

Genetic exceptionalism

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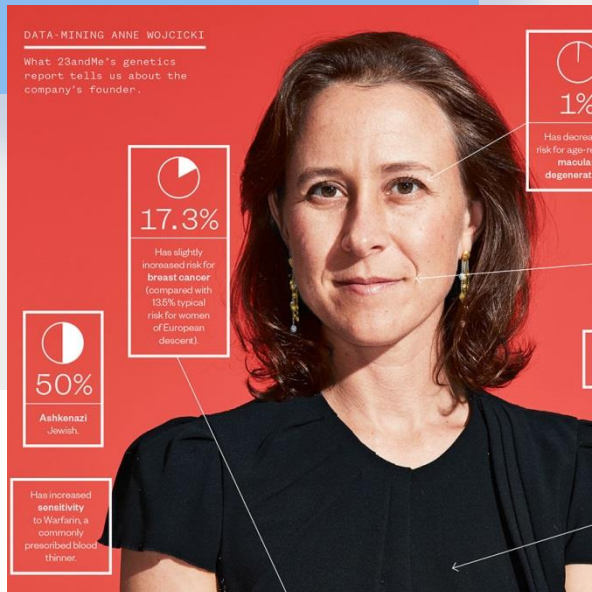
- laws for protection and anti-discrimination (GenDG in DE, GTG in AT, GUMG in CH)
- Protection of individuals (and their relatives) from their own curiosity
- patient/consumers are both capable and better informed about most pros and cons of genetic testing for certain inherited diseases than most physicians
- All medical information is precious, private and deserves vigorous protection
- ensuring that legitimate medical providers have quick and reliable access to it
- Challenging definition of purpose of genetic testing (diagnosing, risk assessment, forensic, lifestyle)
- Post hoc analysis of genetic data is frequent

23andMe's co-founder and CEO Anne Wojcicki (was) married to Google co-founder Sergey Brin



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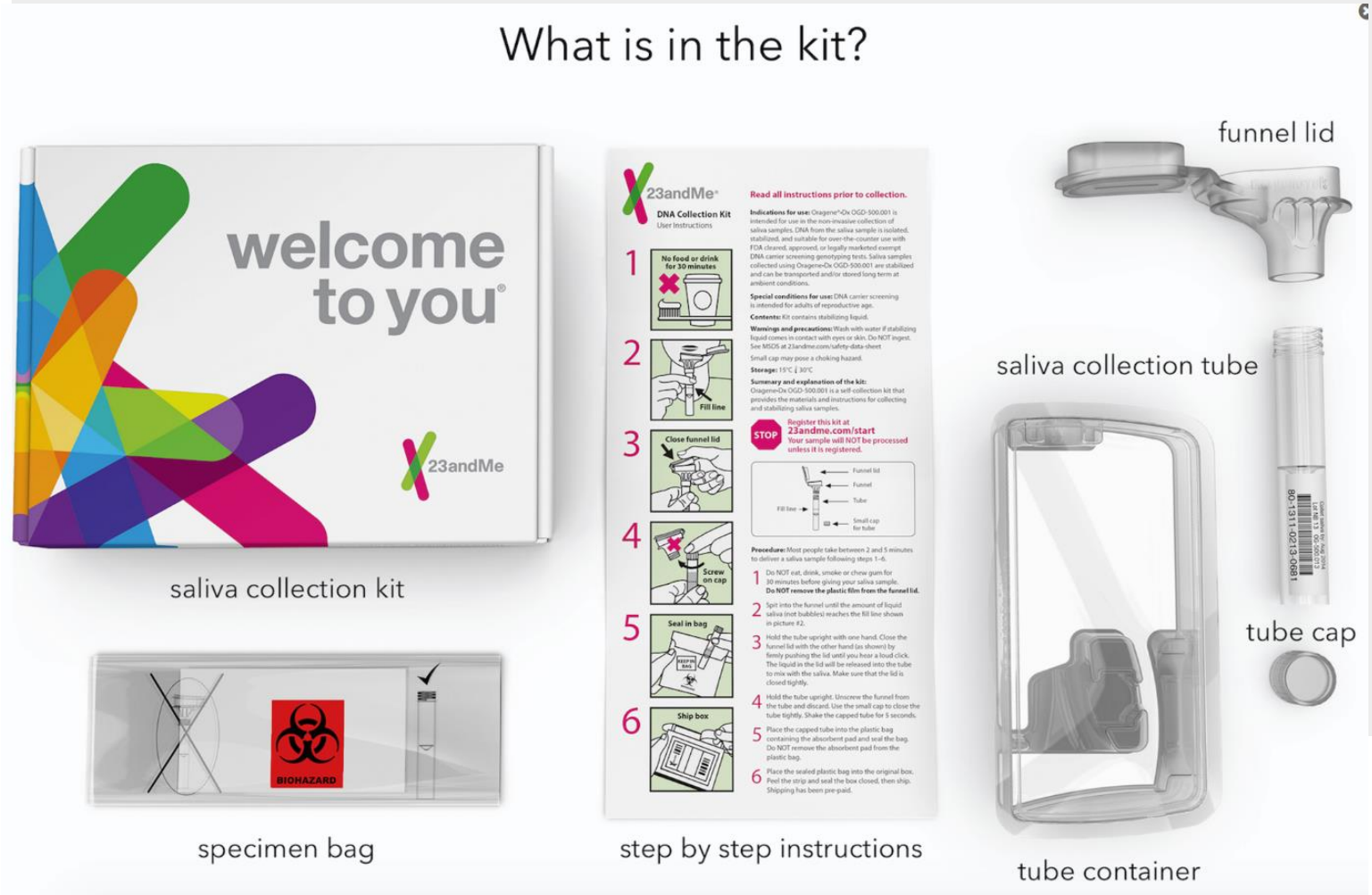
23ANDME GETS FDA APPROVAL FOR DIRECT-TO-CONSUMER GENETIC TESTS

IT'S NOW THE FIRST COMPANY OF ITS KIND TO GET THE FEDS' GO-AHEAD

By Alexandra Ossola Posted October 21, 2015



FDA ORDERS PERSONAL GENOMICS COMPANY 23ANDME TO STOP MARKETING DNA TEST

"FDA IS CONCERNED ABOUT THE PUBLIC HEALTH CONSEQUENCES OF INACCURATE RESULTS."

By Paul Adams Posted November 25, 2013

According to the letter, the FDA has been seeking information needed to approve the test for a while, "including more than 14 face-to-face and teleconference meetings, hundreds of email exchanges, and dozens of written communications":

> **months after you submitted your 510(k)s and more than 5 years after you began marketing, you still had not completed some of the studies and had not even started other studies necessary to support a marketing submission for the PGS. It is now nine months later, and you have yet to provide FDA with any new information about these tests. You have not worked with us toward de novo classification, did not provide the additional information we requested necessary to complete review of your 510(k)s, and FDA has not received any communication from 23andMe since May. Instead, we have become aware that you have initiated new marketing campaigns, including television commercials that, together with an increasing list of indications, show that you plan to expand the PGS's uses and consumer base without obtaining marketing authorization from FDA.**

23andMe has not yet responded publicly.

23andMe

welcome | ancestry | how it works | research | buy | help

Bring your ancestry to life through your DNA.

Discover your ancestral origins and trace your lineage with a personalized analysis of your DNA.

- Ancestry composition
- DNA relatives
- Neanderthal percentage
- Family tree tool
- Maternal and paternal lineages

order now

Pricing

2007 US $999

2012 US $99 (loss leader in order to build a valuable customer database)

October 2015 $199

October 2014 CAN $199 (health related data)

(December 2014) GBP £125 (health related data)

FDA Letters to Genetic Testing Companies

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Company	**Test Name**	*Indication or Claim*
DNA4Life	**Pharmacogenetic Report**	*Intended to predict how patients will respond to more than 120 of the most commonly prescribed medications*
DNA-CardioCheck, Inc.	**DNA-CardioCheck**	*Intended to test for DNA genetic markers linked to thrombophilia, deep vein thrombosis, cardiovascular disease and stroke*
Interleukin Genetics, Inc.	**PerioPredict Genetic Test** **Osteoarthritis Genetic Test** **Weight Management Genetic Test**	*Intended to identify individuals with genetic predisposition for increased risk to diabetes and heart attack, osteoarthritis associated conditions, and obesity-related genotype for weight loss*

www.raps.org

"FDA appreciates that many consumers would like to be informed about their genomes, and their genetic risk for development of future disease. We agree that access to tests through a DTC model can allow consumers to take responsibility for certain aspects of their health, and to learn more about genetics and its contributions to risk, among other probable benefits. We believe that certain types of tests are being appropriately offered through the DTC model, but others may need to demonstrate that they are safe and effective and that appropriate controls are in place to mitigate risks"

Procedure

M.D.

Informiert Patient

Informs patient

STADA Diagnostik

pharmacy

Patient buy STADA voucher (testing incl. VAT)

M.D.

- Draws blood
- Fills in form
- Ships blood

M.D.

Discusses testing result, changes therapy

DNA-testing on behalf of M.D.

Billing center

Invoice (w/o VAT)
Lab testing already paid
Physician fee

Arzthonorar

Patient

Receives optimized and individualized therapy

Conclusions of Lifestyle DTCT

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- DTCT bears severe risks to patients/customers relying on DTCT
- *lacking claims of usefulness and lack of harm*
- *Bogus >>> evidence*
- *Negative impact on medical commons (psychic harm, follow up testing)*
- *Exclusive situation of healthcare as well as EBM is jeopardized by DTCT*
- *Particular risks of healthcare professsionals using DTCT data!*
- *Essential and medically sound regulations of GenDG are leveraged by DTCT*