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

Priv.-Doz. Dr. med. Matthias Orth
Institut für Laboratoriumsmedizin
Adlerstr. 7 DE-70199 Stuttgart
Tel + 49 711 6489 2760
matthias.orth@vinzenz.de
Potential conflict of interest

DGKL (section laboratory management)
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

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

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

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
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)

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

§ 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

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

Lab Tests

POCT

DTCT

Lifestyle

Animal testing, food testing

Commercial lab testing
Foodstuff IgG₄

Evidence based medicine

Lab Tests

Healthcare

POCT

DTCT

Continuous glucose monitoring

Lifestyle

Commercial lab testing

Animals, testing, food testing
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

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. 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.

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. 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

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).
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.”

“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.”


Partnership with
- Cleveland Clinic to decrease the cost of lab tests
- Pennsylvania insurers
- AmeriHealth Caritas
- Capital BlueCross
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

Personalisiertes Health Coaching mit den Vimedea Tests

- Fitness
- Performance
- Nutrition
- Vitamin D
- Omegas
- Premium
- Age Vitality
- Basic

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

Vimedea.de
Zweckbestimmung
Medizinprodukt


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.

Unsere Partner und Zertifizierungen:
IgG₄ against foodstuff
Obligation to render qualified services and in person

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“
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 require 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.
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 …
<table>
<thead>
<tr>
<th>Test Description</th>
<th>EBM</th>
<th>GOÅ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alanine Aminotransferase (ALT)</td>
<td>€0.22</td>
<td>€2.33</td>
</tr>
<tr>
<td>Amylase</td>
<td>€0.36</td>
<td>€2.99</td>
</tr>
<tr>
<td>Antinuclear Antibodies, Screen (ANA)</td>
<td>€6.57</td>
<td>€29.73</td>
</tr>
<tr>
<td>Aspartate Aminotransferase (AST)</td>
<td>€0.22</td>
<td>€2.33</td>
</tr>
<tr>
<td>Calcium</td>
<td>€0.22</td>
<td>€2.33</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>€0.22</td>
<td>€2.33</td>
</tr>
<tr>
<td>Cortisol, Total</td>
<td>€5.58</td>
<td>€14.57</td>
</tr>
<tr>
<td>C-Reactive Protein (CRP)</td>
<td>€1.04</td>
<td>€5.83</td>
</tr>
<tr>
<td>C-Reactive Protein, High Sensitivity (hsCRP)</td>
<td>€4.41</td>
<td>€11.66</td>
</tr>
<tr>
<td>Creatine Kinase</td>
<td>€0.22</td>
<td>€2.33</td>
</tr>
<tr>
<td>Estradiol</td>
<td>€4.14</td>
<td>€20.40</td>
</tr>
<tr>
<td>Follicle Stimulating Hormone (FSH)</td>
<td>€4.05</td>
<td>€20.40</td>
</tr>
<tr>
<td>Luteinizing Hormone (LH)</td>
<td>€4.05</td>
<td>€20.40</td>
</tr>
<tr>
<td>Progesterone</td>
<td>€3.42</td>
<td>€20.40</td>
</tr>
<tr>
<td>DHEA-S</td>
<td>€6.21</td>
<td>€20.40</td>
</tr>
<tr>
<td>Prolactin</td>
<td>€4.14</td>
<td>€20.40</td>
</tr>
<tr>
<td>Testosterone, Free</td>
<td>€2.25</td>
<td>€20.40</td>
</tr>
<tr>
<td>Testosterone, Total</td>
<td>€2.25</td>
<td>€20.40</td>
</tr>
</tbody>
</table>
Quadruple times more outliers in DTCT than in real lab tests.
Genetic exceptionalism

- 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 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
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

Pricing
2007 US $999
2012 US $99 (loss leader in order to build a valuable customer database)
October 2015 $199
September 2016 $149
23andMe's co-founder and CEO Anne Wojcicki (was) married to Google co-founder Sergey Brin

Accelerating research. A new way.

Your genetics could help find the answer to someone else's disease.

In order for scientists and researchers to accelerate healthcare, they need large sets of data...from all of us.

Your research participation could contribute to findings in disease prevention, better drug therapies, disease treatments and ultimately, genetic paths to cures.

Once you purchase your kit, you will have the choice to join this research revolution.

“I think most people don't think they can help with research and discoveries, we're not scientists or major contributors, that's someone else – but here is something I can do.”

23andMe Customer

order now
## FDA Letters to Genetic Testing Companies

<table>
<thead>
<tr>
<th>Company</th>
<th>Test Name</th>
<th>Indication or Claim</th>
</tr>
</thead>
<tbody>
<tr>
<td>DNA4Life</td>
<td>Pharmacogenetic Report</td>
<td><em>Intended to predict how patients will respond to more than 120 of the most commonly prescribed medications</em></td>
</tr>
<tr>
<td>DNA-CardioCheck, Inc.</td>
<td>DNA-CardioCheck</td>
<td><em>Intended to test for DNA genetic markers linked to thrombophilia, deep vein thrombosis, cardiovascular disease and stroke</em></td>
</tr>
<tr>
<td>Interleukin Genetics, Inc.</td>
<td>PerioPredict Genetic Test</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Osteoarthritis Genetic Test</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Weight Management Genetic Test</td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>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</em></td>
<td></td>
</tr>
</tbody>
</table>

"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.
- Informs patient
- STADA Diagnostik

pharmacy
- Patient buy
- STADA voucher (testing incl. VAT)
- and MWSiC

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

Patient
- Receives optimized and individualized therapy

Humatrix

STADA Diagnostik
Conclusions of Lifestyle DTCT

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