



## 66th edition of the Biology Innovation Days



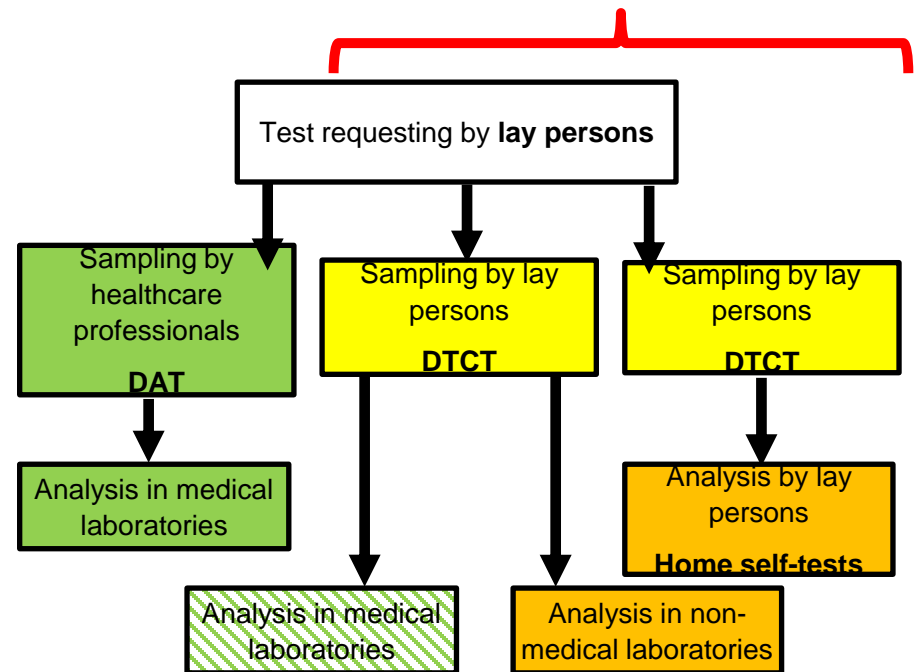
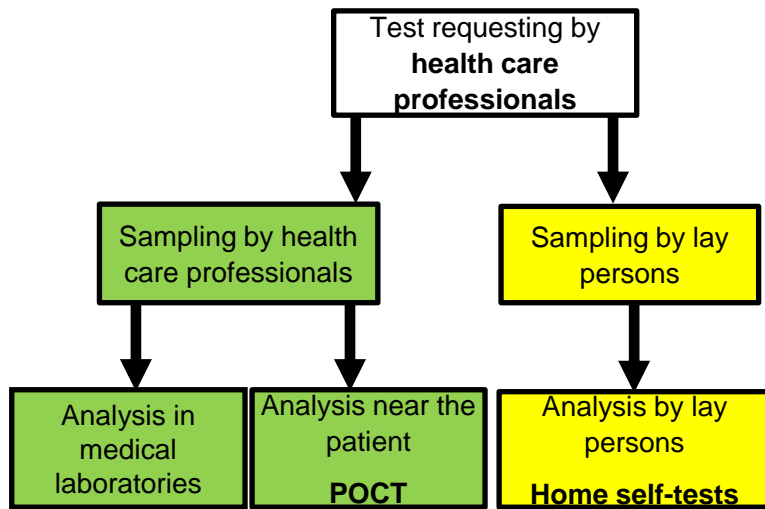
# The whys and hows of direct-to-consumer testing (DTCT)

- Matthias Orth, MD PhD\*

\* No conflict of interest

- Vinzenz von Paul Kliniken DE-Stuttgart and Heidelberg University Medical Faculty of Medicine DE-Mannheim

# Definition of DTCT



# Healthcare paradigm modified by P4 Medicine

- Predictive
- Preventive
- Personalized
- Participative

individual's **participation** as the key

effective **self-management**

**decision sharing** with patients for their clinical-therapeutical approach

**novel technologies to implement patients' participation in disease management**

improvement in **patient reported outcomes**

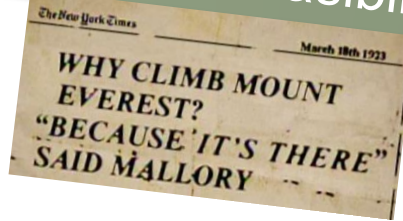
self-empowerment of patients

Gadget  
(homo ludens)

Avoiding  
discrimination  
(STD)

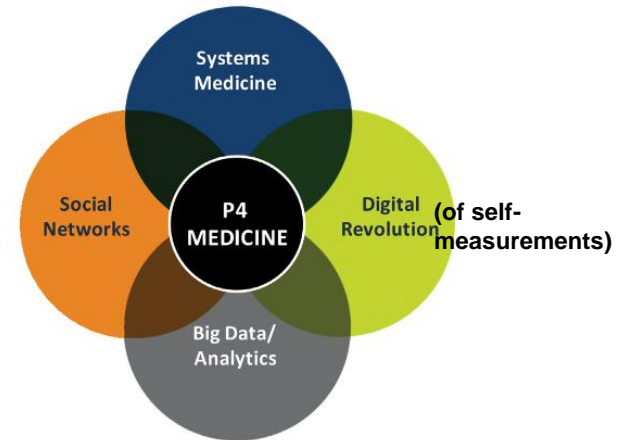
Business model

Technical feasibility



Alternative facts

# Why DTCT?



Redefining the role of the physician in laboratory medicine in the context of emerging technologies, personalised medicine and patient autonomy ('4P medicine'). J Clin Path 2019;**72**:191-97 doi: 10.1136/jclinpath-2017-204734

Leroy Hood DOI: [10.1016/j.gpb.2018.02.002](https://doi.org/10.1016/j.gpb.2018.02.002)

# Challenges of electronic health records



European  
Commission

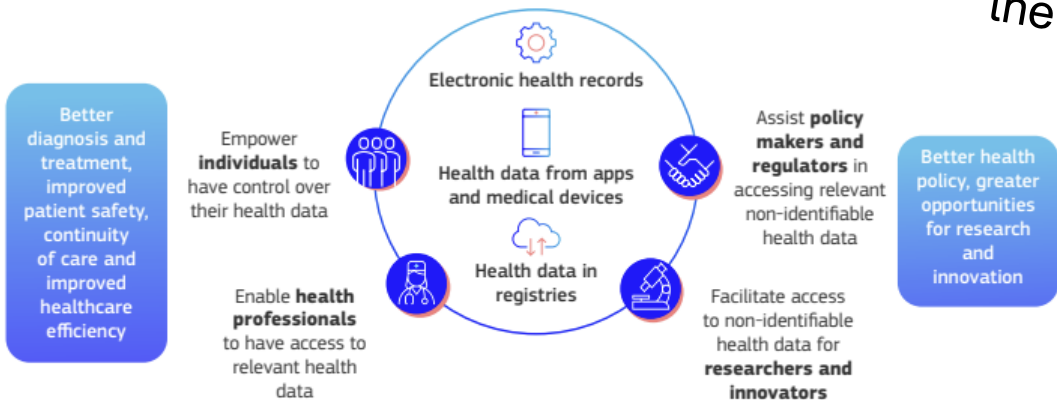
## EUROPEAN HEALTH DATA SPACE

#EUDigitalHealth

### OBJECTIVES

- ✓ Empower individuals through better digital access to their personal health data; support free movement by ensuring that health data follow people;
- ✓ Unleash the data economy by fostering a genuine single market for digital health services and products;
- ✓ Set up strict rules for the use of individual's non-identifiable health data for research, innovation, policy-making and regulatory activities.

EHDS1:  
These consist of the exchange of original clinical documents, **laboratory results/laboratory reports**, medical images, and hospital discharge reports, with further data categories of the full health record to follow.



## *Federal legislations to safeguard the patients (Medical Act)*

- **Restricts practicing medicine to (licensed) physicians**
- **diagnosing illnesses**
- prescribing diagnostic examinations
- using risky / invasive diagnostic techniques
- **determining medical treatment**
- **prescribing medications**

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- **clinical monitoring of patients with problematic health**
- providing pregnancy care/deliveries
- **deciding to use isolation measures**

## ***Technical terms and federal/EU legislations to safeguard the patients***

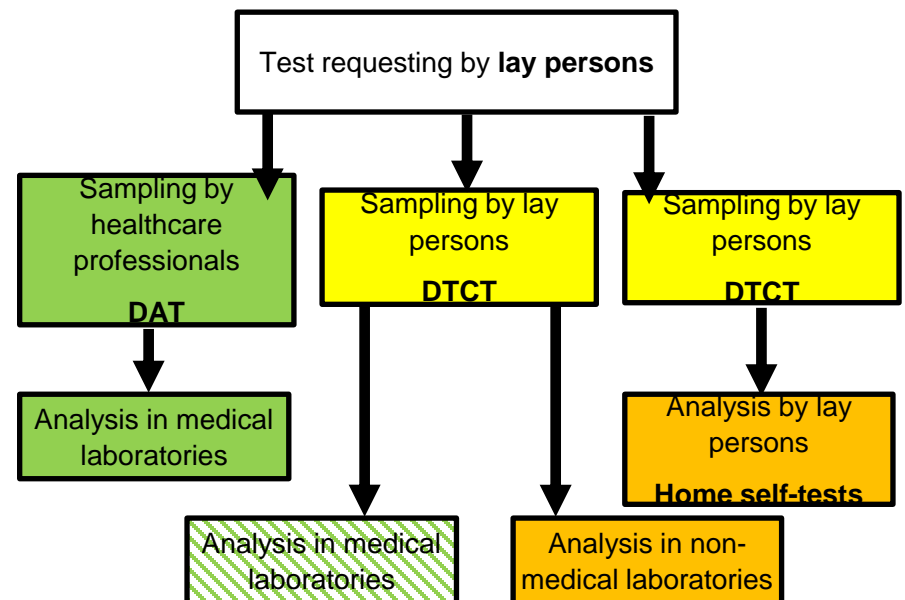
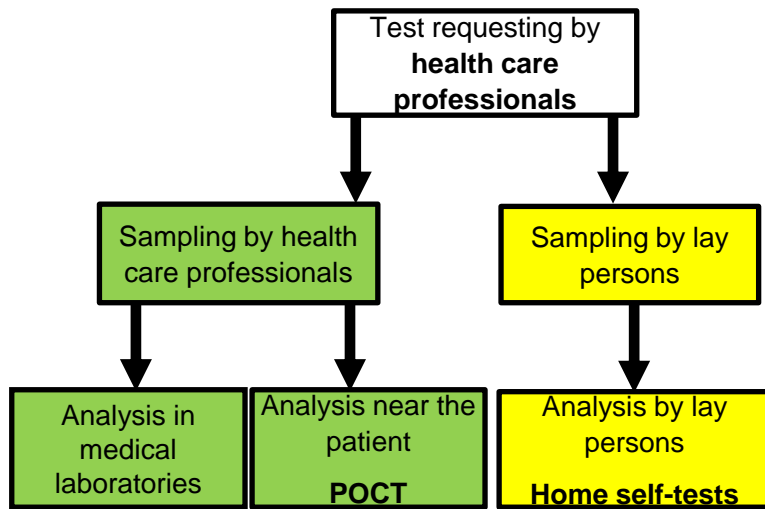
- IVDR (intended use, process of proven tests)
- Staff with proven qualifications (national diploma)
- Testing sites inspected
- Reporting standardized (LOINC, SNOMED-CT, UCUM, EUDAMED, UDI)
- Preanalytics, analytics, postanalytics (“brain-to-brain loop”)
- Mandatory process controls (IQC and EQA)
- Traceability chain, certified reference materials
- Complete quality management system covering pre-, post- and analytics DIN EN ISO 15189:2023-03

„Controlled“ process

„Can be controlled“ process

„Uncontrolled“ process

# Definition of DTCT





# Defining the intended use / intended purpose of an IVD test /device

## •Clinical question/clinical scenario

- Screening, monitoring, diagnosis, prognosis, prediction, companion diagnostic, ...
- Physiological / pathological state, congenital physical / mental impairments, predisposition, compatibility with transplant recipients, prediction of treatment response or reactions, TDM

## •availability and use of other diagnostics

- Measurand, matrices
- Measurement type (nominal, ordinal, interval, ratio)
- Commutability to certified reference materials / methods (decision limits)
- Target population and prevalence of condition

## •Appropriate level of performance:

- Clinical performance: necessary clinical performance, acceptable diagnostic uncertainty
- Analytical performance: analytical performance guarantees level of clinical performance
- Equivalence of performance claims of devices available on the market

# Special Report

## “Sink Testing”—Myth or Reality?

Judith L. Adamson, MT(ASCP)SBB

*(Physician's Automated Laboratory, Bakersfield, CA)*

DOI: 10.1309/PGNGDM59CAP4C9HX

The definition of “sink testing,” although not found in any dictionary, is the reporting of a value when in fact no testing has been performed. Another name for this practice is to “dry lab”—reporting a test value when the test tubes were unused or “dry.” This may include a range of acts from “writing-in” QC or PM results without performing the process or test, to far more serious acts as reporting patient results without ever performing the test.

Although we would all like to think that this practice is in fact a myth or laboratory joke, unfortunately even in the current laboratory environment, there is evidence that this unethical practice may occur. The problem is proving that a “professional” has actually committed intentional fraud. It is easier to think of an individual as lacking competence rather than lacking integrity. A situation I heard about several years ago involved a blood bank error that was discovered by the nurse preparing for a transfusion. The technologist had labeled the units as A POS on the cross-match tags. In making the pre-infusion checks, the nurse noted that the units were clearly labeled as O POS. When the laboratory supervisor reviewed the compatibility testing records it was noted that the technologist had recorded the reactions for A POS on the unit group/type confirmation. The technologist stated that she had not noticed the error and had followed all the correct laboratory procedures. Question, was this an error or a deliberate act of “sink testing”? It is impossible to prove.

been made. This may appear extreme, but it is probably the most common reaction by administrators. Do not investigate the charges—rather, eliminate the individual that is making the charges. Make it go away. Eliminate the problem.

In our current litigious climate and under control of the human resource departments, even when there are serious suspicions, the only action that a laboratory will take is termination. Get rid of the problem employee, or pass them on to another laboratory. However, in the profession as a whole, this response only creates a larger problem. Not only does it allow unethical technologists to continue to work, but it presents an image of a profession that is unwilling to make ethics a priority over public image. As I attempted to research for this article, it became obvious that this is not a subject often discussed or about which much is written. Most professionals do not want to believe that a fellow professional is capable of “sink testing.” There appears to be few published reports that address the problem of “sink testing,” so there is no way to estimate the size of the problem as long as it remains unconfirmed, unreported, and not discussed. Additionally, it remains unacknowledged within the profession.

A larger issue is the cost of “sink testing.” There is the overall cost to laboratories and the profession. Yet on a more personal scale, there is the cost to the individual patient. Recently while performing monthly quality assurance, a laboratory supervisor

The screenshot shows the European Patent Office (EPO) website. At the top, there is a search bar with 'Site search' and 'Patent search' tabs. Below it, a navigation menu includes 'Home', 'Searching for patents', 'Applying for a patent', 'Law & practice', 'News & issues', and 'Learning & events'. The 'News & issues' section is active, showing a breadcrumb trail: 'Home → Learning & events → European Inventor Award → The finalists → 2015 → Holmes'. The main content area features a profile for 'Elizabeth Holmes (USA)', identified as a 'Finalist for the European Inventor Award 2015'. A video player shows a close-up of her hand holding a small object. Below the video, there are links for 'Videos' (including 'Elizabeth Holmes in her own words' and 'About the invention') and 'Category: Non-European Countries'. The page also lists her sector as 'Medical technology', company as 'Theranos, Inc.', and patent numbers 'EP2205988' and 'EP1662987'.

emilic.nup.com/labmed/article/3711652/2504451

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 woman with diabetes reduced the costs ... of tests she required from 711 € using traditional blood analysis methods down to 28 € using Holmes's technology



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- Get It Tomorrow
- Department**
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- Allergy Tests
- Thyroid Disorder Tests
- Vitamins, Minerals & Supplements
- Vitamin B12
- Cleaning Agents
- Special Cleaners
- See All 5 Departments

**Customer Reviews**

- ★★★★★ & Up
- ★★★★☆ & Up
- ★★★☆☆ & Up
- ★★☆☆☆ & Up

**Brand**

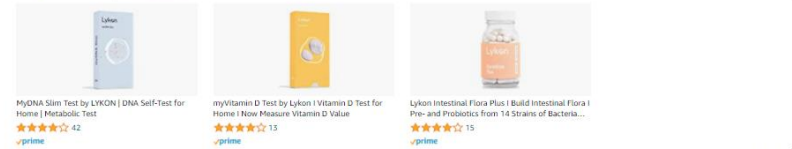
- CERASCREEN

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- 50 - 100 EUR
- 100 - 200 EUR

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Oder Anmeldung mit

Das Angebot gilt nur für Neukunden. Mit der Annahme dieses Angebots erklären Sie sich mit den Teilnahmebedingungen einverstanden.

Powered by Talkable

Johannes, 48



„Ich hatte zum ersten Mal in meinem Leben keinen nennenswerten Heuschnupfen mehr.“

**JOHANNES GESCHICHTE**

Seit meiner Kindheit leide ich jeden Frühling unter starkem Heuschnupfen: juckende rote Augen, ständiges Niesen, juckender Gaumen und für jeweils ca. 1 Woche sogar asthmatische Beschwerden.

*Selbst Medikamente haben teilweise nicht mehr geholfen.*

Da Allergie ja mit einem überreagierenden Immunsystem zu tun hat, und wiederum das Immunsystem eng mit dem Darm verbunden ist, kam ich irgendwann darauf, mich mehr mit meiner Darmgesundheit zu beschäftigen. Die Probiotika führten tatsächlich zu einer starken Verbesserung meines Heuschnupfens. Als ich dann irgendwann Lykon entdeckt habe, dachte ich, dass Lebensmittelunverträglichkeiten ebenfalls ein wichtiger Faktor sein könnten, weil diese auch zu einer starken Reizung des Darms führen können. Deswegen kaufte ich den myNutrition100.

*15 Minuten Aufwand und der Test war erledigt.*

Mir gefällt, dass ich für den Test nicht extra zum Arzt musste, und ich den Test ohne Probleme zu Hause durchführen konnte. Ein paar Tage später hatte ich dann auch schon das Ergebnis in meinem Lykon-Portal - sehr gut und verständlich aufgearbeitet. Da ich gegen relativ viele Lebensmittel Unverträglichkeiten aufweise, konzentrierte ich mich auf die kritischsten Lebensmittel und vermied diese möglichst konsequent, was mir anfänglich schon etwas schwerfiel.

*Meine angepasste Ernährung zeigte ganz schnell einen sehr positiven Effekt auf meinen Darm.*

An Tagen, an denen ich doch mal nach den verbotenen Lebensmitteln griff, spürte ich dagegen umgehend einen negativen Effekt. Die beste Nachricht für mich aber war: Ich hatte diesen Frühling zum ersten Mal in meinem Leben (und ich bin bereits 48 Jahre alt) keinen nennenswerten Heuschnupfen mehr. Ich konnte es kaum glauben - und auch mein Umfeld war sehr erstaunt. Sicherlich spielen viele Faktoren bei Allergien eine Rolle, aber ich bin der festen Überzeugung, dass der Lykon-Test (und natürlich das Einhalten der daraus folgenden Regeln) meine Beschwerden deutlich gelindert hat.



prerequisites for granting a “Heilpraktiker” license

age >25 years

existing secondary school certificate

health suitability for planned activity

police certificate of good conduct

40 MC questions

Reichsgesetzblatt		
Teil I		
1939	Ausgegeben zu Berlin, den 20. Februar 1939	Nr. 30
Inhalt		
17. 2. 39	Gesetz über die berufsmäßige Ausübung der Heilkunde ohne Bestallung (Heilpraktikergesetz) .....	251
17. 2. 39	Gesetz über die Beförderung der Hochschullehrer (Hörsaalbeförderungsgesetz) .....	252

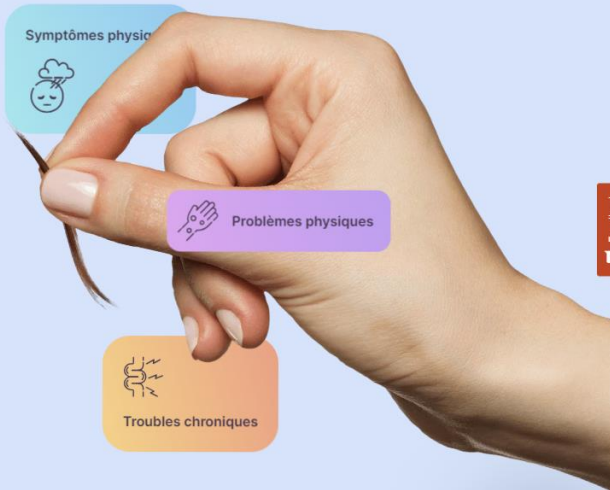
Medicross testing is a „Heilpraktiker“ (quacksalver) running a laboratory

Method: **Bioresonance therapy** is a pseudoscientific medical practice in which it is proposed that electromagnetic waves can be used to diagnose and treat human illness (Wikipedia)

# Comprendre ton corps

Découvre maintenant de manière simple si tu ne tolères pas bien quelque chose ou si tu pourrais avoir un besoin accru en micronutriments.

Fais-toi tester maintenant



Feedback

↓ En savoir plus

★ CUSREV 4,65 ★★★★★ 🐾

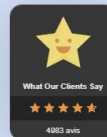
# Adapté à toi

Chez nous, tu reçois ta formule nutritive personnelle dans des gélules pratiques à avaler. Elles sont fabriquées individuellement par notre pharmacie partenaire et livrées chez toi.



↓ En savoir plus

★ CUSREV 4,65 ★★★★★ 🐾 Animaux aussi



## Intended use / intended purpose of testing ?

Everlywell has modernized lab testing by bringing access **to credible, validated laboratory tests** that are initiated and collected by you in the comfort and convenience of your own home. We aim to empower individuals to be proactive about their health, and our commitment to **quality and accuracy is the same that you would expect from your doctor's office**. Through the combination of best-in-class science, physician oversight, and rigorously validated collection methods and service, we ensure the best quality testing by working with labs that meet the following standards:

Everlywell offers health and wellness solutions including laboratory testing for wellness monitoring, informational and educational use. With the exception of certain diagnostic test panels, list available [here](#), **the tests we offer access to are not intended to diagnose or treat disease**. None of our tests are intended to be a substitute for seeking professional medical advice, help, diagnosis, or treatment. For regulatory reasons, our tests are not available in NY with the exception of COVID-19.

# Intended use / intended purpose of testing ?



CASC Testkits bieten einen persönlichen Ansatz, um die Bedürfnisse des eigenen Körpers zu verstehen. Das ist ein Schritt nach vorn im persönlichen Gesundheitsmanagement und ermöglicht es Ihnen, Ihren Lebensstil auf der Grundlage Ihrer individuellen Ergebnisse anzupassen.

**Dr. med. Sven Jungmann, M.SC., M.P.P.**  
Führender Experte für Telemedizin und Digital Health

6 € per dipstick



1. Streifen eintauchen

Sammle deinen Urin in einem Gefäß und halte den Teststreifen kurz in die Probe.



2. Foto aufnehmen

Lege den Teststreifen auf die schwarze Fläche der Farbkarte und mache ein Foto über die CASC App. Die Software analysiert das Foto.



3. Ergebnisse erhalten

Innerhalb weniger Sekunden hast du deine persönlichen Ergebnisse und Vorschläge übersichtlich auf dem Smartphone.



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Dieses Produkt eignet sich nicht zur Diagnose von Krankheiten, einschließlich der Bestimmung des Gesundheitszustandes, der Heilung, Linderung, Behandlung oder Vorbeugung von Krankheiten oder den daraus resultierenden Zuständen.

# Intended use/intended purpose of testing ?

thebmj covid-19 Research ▾ Education ▾ News & Views ▾ Campaigns ▾ Jobs

**News**

## Smart toilets, bored students, why crowds gather, and tasty rocks—it's the 2023 Nobel Awards

BMJ 2023 ; 382 doi: <https://doi.org/10.1136/bmj.p2116> (Published 15 September 2023)  
Cite this as: BMJ 2023;382:p2116

Article Related content Metrics Responses

Janice Hopkins Tanne

Author affiliations ▾



We have smartphones and smart watches, so why not smart toilets? Seung-min Park and his colleagues from Stanford University School of Medicine would like people to use the Stanford toilet, a smart toilet that monitors their excretions much as a smart watch counts their daily steps. For this achievement the team won the 2023 Ig Nobel Award for Public Health.<sup>1 2 3 4</sup>

Park told *The BMJ* he has met some resistance to the Stanford toilet. "There's a huge perception of human excreta as taboo," he said. He got a "brutal rejection" from a major science foundation that said his project violated decorum.

The Stanford toilet uses a variety of technologies including a urinalysis dipstick test strip, a computer vision system for defecation analysis, an anal print sensor paired with an identification camera, and a telecommunications link to monitor and quickly analyse the substances that people excrete. It could be linked to a person's electronic health record.

The smart toilet device could be fitted beneath existing toilet seats, fit into ordinary daily routines, and passively record health information, Park explained. It would record non-invasive measurements of excreta for precision health—preventive, continuous monitoring of health measures. A fingerprint sensor on the flush lever would identify the user at the end of each ...

This study was funded by the National Institutes of Health (grants UL1 TR001085 and T32 CA118681)



# DTCT Cancer Screening: PanTum detect



4.7/5



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KATEGORIE: PRIVATE KRANKENVERSICHERUNGEN  
**Krebs-Scan**  
HanseMerkur Krankensicherung

## Werbung

# Ein Pfund Kaffee mit Bluttest bitte

Michael Schmedt

Die Marke Tchibo steht für Kaffee und viele mehr oder minder praktische Dinge, sogenannte Konsumgüter, die man in den mehr als 500 deutschen Tchibo-Filialen oder im Onlineshop bestellen kann. Sicher nicht steht Tchibo für Krankenhaus-Zusatzversicherungen. Dennoch findet man solch ein Angebot auf der Website des Unternehmens. Grund ist eine Kooperation mit der privaten Krankenversicherung HanseMerkur. Bis vor wenigen Wochen stand auf der Website von Tchibo zwischen Kaffee, Klamotten und Gartenmöbeln auch eine Werbung für ein „innovatives Programm der HanseMerkur“. Dieses sollte man

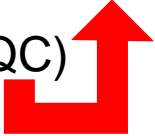

Dieser Vorgang lässt einen nachdenklich zurück und macht wieder einmal deutlich, wie schnell Gesundheit zum Geschäft wird. Dass dann noch ein offensichtlich nicht evidenzbasiertes medizinisches Verfahren angepriesen wird, macht es auch gefährlich. Falsch-positive Ergebnisse können bei den Betroffenen zu großer Unsicherheit und zu strahlenintensiven Folgeuntersuchungen führen, das heißt zu unnötigen psychischen und gesundheitlichen Belastungen.

Dass Krankenversicherer Angebote machen, die eine Evidenz vermissen lassen, ist nicht neu. Man denke nur an die Diskussion um homöopathische Arzneimittel.

Deutsches Ärzteblatt | Jg. 120 | Heft 37 | 15. September 2023

# DTCT Cancer Screening: IFOBT (immunological fecal occult blood testing)

Intended purpose: detecting elevated fecal hemoglobin concentrations as an indicator of early stages of colon cancer (en lieu of colonoscopy)

1. Preparation of standardized stool suspension (Class A device for professional use)
2. Shipping suspension to laboratory (postal mail)
3. Testing for hemoglobin (IVDR CE marked, EQA and IQC) 
4. Reporting by lab specialists 

Challenges:

concentration of stool suspension too low

Degradation of hemoglobin during storage

Reference range too low (too many follow-up colonoscopies (physical and psychological harm

In study: Sensitivity 39,0 % (95 %-CI: 34,1- 44,1 %), Specificity of 92,9 % (95 %-CI: 91,9-93,7 %)

# Challenges



- no quality criteria have to be followed if laboratory tests are performed by non-health care professionals allowing free movement of services under 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**.*

- Definition of medical lab is different among countries
- (same test performed from animal specimen, food stuff, lifestyles samples, and human medical samples!)

(wrong) doing creates facts ...

With the amending ordinance of the Medical Devices Dispensing Ordinance, the influenza rapid test is to become freely available for sale. To justify the necessity, reference is made to **1. mercantile circumstances** ("combination tests are currently offered with which not only SARS-CoV-2, but also influenza A/B and RSV can be tested"), **2. to framework conditions under European law**, and **3. to learned handling through the use of Corona self-tests** in the pandemic.



KBV  
KASSENÄRZTLICHE  
BUNDESVEREINIGUNG



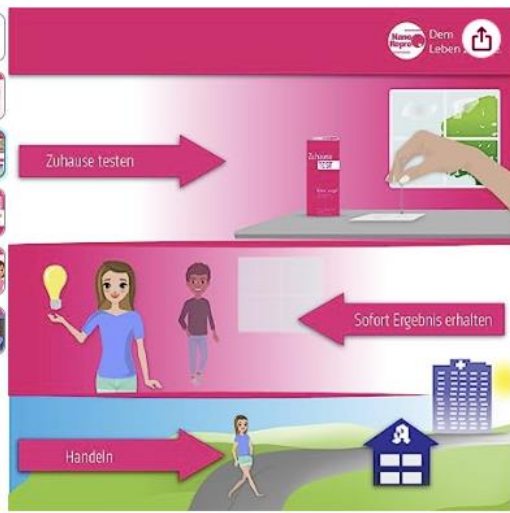
Stellungnahme  
der Bundesärztekammer

DRITE VERORDNUNG ZUR ÄNDERUNG  
DER MEDIZINPRODUKTE-  
ABGABEVERORDNUNG

STELLUNGNAHME DER KBV ZUM REFERENTENTWURF DES  
BUNDESMINISTERIUMS FÜR GESUNDHEIT VOM 13. FEBRUAR 2023

zum Referententwurf einer Dritten Verordnung zur Änderung der  
Medizinprodukte-Abgabeverordnung (MPAV)





Roll over image to zoom in



### Home Test Iron Deficiency Pack of 1

Brand: NanoRepro  
3.6 ★★★★★ 9 ratings

€9<sup>95</sup> (€9.95 / stück)

prime One-Day

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Save 5% on 4 select item(s) Shop items

Quantity: 1

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5 x 5 Nasal Antigen Laietest Self-Test CE 1434 Self-Test Also for the Omicron Version

10<sup>99</sup> € incl. VAT

Sponsored

it Iron + Cerascreen Vitamin D Test Kit + CERASCREEN Vitamin B12 Test Kit - Vitamin B12 Levels Easily Determine by Self-Test from...

€24<sup>95</sup> (€24.95/stück) + €39<sup>00</sup> (€39.00/stück)

Total price: €73.90

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FREE delivery **Tomorrow, 19 June**. Order within 8 hrs 47 mins

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New (4) from €9<sup>95</sup> prime FREE One-Day

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€9.95 (€9.95 / stück) Add to Basket & FREE Delivery  
Sold by: MSZ Service & Logistik

€14.95 (€14.95 / stück) Add to Basket & FREE Delivery  
Sold by: NanoRepro AG

“FerritinCHECK detects a Ferritin concentration of 20 ng/mL and higher with a negative result (no iron deficiency)”.



## Curious Starter Pack

369.00 EUR

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Contains 1 Bloom Lab, 2 Bloom Ferritin Tests and 2 Bloom Thyroid

Tests

Requires Bloom App.

**14,20 € costs in Germany**



SPECIAL ARTICLE [FREE PREVIEW](#) [ARCHIVE](#)

## Protecting the Medical Commons: Who Is Responsible?

Howard H. Hiatt, M.D.


Medical care are clearly finite, but demands on those resources are growing rapidly.

July 31, 1975

N Engl J Med 1975; 293:235-241

DOI: 10.1056/NEJM197507312930506

Opinion –  
**How reliable is the egg timer blood test?**  
14 June 2023  
Can it really predict your chance of conceiving?

repro.me    [Speak to a Fertility Nurse](#)

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**COVID-19 - Advice for Patients**

Repromed > Fertility Treatments > Egg Timer Test

# Egg Timer Test

The Egg Timer test estimates Ovarian Reserve – the number of quality eggs left within the ovaries. This gives an indication of the likely fertility status of a woman. The test involves a single blood test and pelvic ultrasound scan between days 3 to 5 of the menstrual cycle. The blood test measures levels of several different hormones, and combined with the scan result gives an estimate of the Ovarian Reserve.

### Why have this test?

Many women delay starting a family for various reasons. However, fertility declines with age and problems may develop. An early indication of fertility status may help in deciding whether to start a family sooner or later.

### What if your Ovarian Reserve is low?

Once the ovary runs out of eggs, the body isn't able to produce any more, and it usually leaves the lowest quality eggs till last. Even IVF treatment will not dramatically improve fertility if there are only a few poor quality eggs left within the ovaries. If you are in a relationship and have a low ovarian reserve, the best option is to go ahead and try for children as soon as possible. If a woman does undergo premature menopause, using donor eggs is a viable option that is available through Repromed.

Questions? Chat with a Fertility Nurse on [08 8333 8111](tel:08-8333-8111) or fill out the [enquiry form](#) »

### Download your free Tips to Boost Your Fertility guide

Download your very own fertility guide to maximise your chances of conceiving.

Happy to receive occasional news

Should you contact us, your information and nature of your enquiry will be documented on a file.

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It also [can't reliably predict](#) menopause [timing](#) for individual women.

Because of this, the American College of Obstetricians and Gynaecologists [strongly discourages](#) AMH testing in women who are not seeking fertility treatment. It states the test:

“  
*should not be ordered or used to counsel women who are not infertile about their reproductive status and future fertility potential.*  
”

No similar guidance has been published by the relevant colleges in Australia.

## Who gets AMH tests and why?

The test isn't Medicare-subsidised. Most AMH tests are paid for privately by consumers, costing around A\$80-\$120. Because of this, data on current test usage is not publicly available.

To find out how many women in Australia are accessing AMH testing and why, we conducted the [first investigation](#) into its use in Australia.

We surveyed a representative sample of 1,773 women aged 18 to 55, recruited through the [Life in Australia](#) national study.

We asked them if and how they had heard about AMH testing, whether they had ever had an AMH test, their main reason for testing and how they accessed the test.

Our results, published today, show 13% of the women had heard about AMH testing and 7% had had an AMH test.

Alle /

# Cycle-Check

Alle

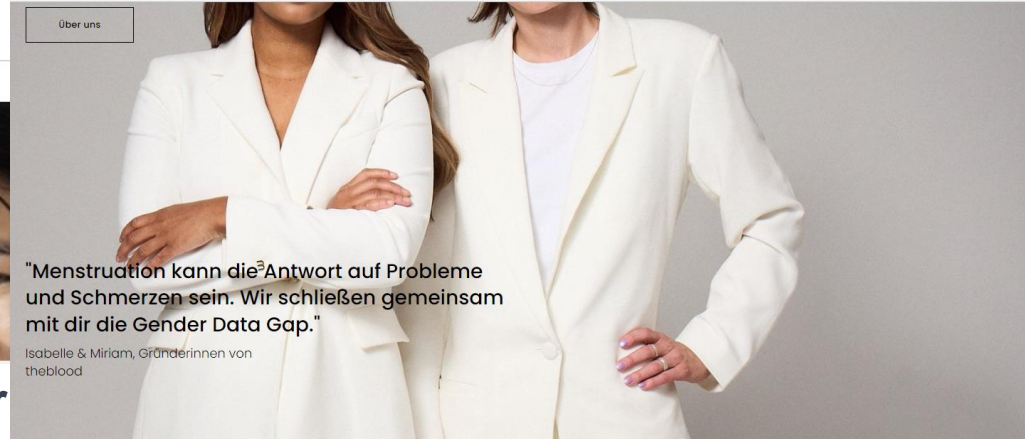
## Cycle-Check

Hey Period Shake

theblood Menstrual Cup

theblood Cap

theblood Hoodie



### Unterstütze deinen Zyklus

Unser Proteinshake wird zum festen Bestandteil deiner Zyklusroutine und ist der ultimative Begleiter.

Wir verstehen wie einzigartig dein Körper in dieser Zeit ist. Unser Produkt ist darauf abgestimmt deine Nährstoffbedürfnisse während des gesamten Zyklus zu unterstützen.

Lass uns gemeinsam dafür sorgen, dass du dich in jeder Phase deines Zyklus optimal fühlst.

[Jetzt shoppen](#)



**29,90 €**

- Discover our first softanalysis of your menstrual blood.
- Use the Cycle-Check and optimize your cycle for maximum well-being.
- Learn more about your menstrual blood and the unique characteristics of your sample.
- Manage pain and discomfort more effectively to improve your daily life.
- Innovation takes time— Our prototype does not include a biomarker analysis



# Over medicalization

*medicine has substituted religious institutions:  
authority of therapist instead of a priest  
deviation in terms of sickness rather than sin or crime*

**maximization of lifestyle, potential, health and quality of life** becomes almost obligatory

negative judgments are directed toward those who will not, for whatever reason, adopt an **active, informed, positive, and prudent relationship to the future**

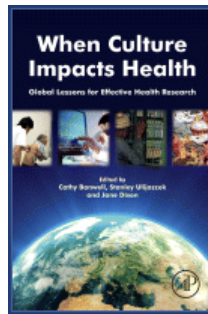
new global bio-economy has developed in which **health, disease, and other vital processes** become sites of **entrepreneurship, capital investment, and sources of wealth**

In the resulting **medical marketplace**, pharma and biotech companies offer new technologies of selfhood that promise to help individuals **enhance their capacities and achieve their aspirations as well as treat their illnesses**

**non-existent diseases and marketing-created health needs**

medicalization as continuum from “too little” to “too much” medicine

•DOI: [10.1007/s11019-018-9850-1](https://doi.org/10.1007/s11019-018-9850-1)



# High rate of FALSE POSITIVES in DTCT

Quadruple times more outliers in DTCT than in real lab tests

© American College of Medical Genetics and Genomics

ORIGINAL RESEARCH ARTICLE

Genetics  
inMedicine

Open

## False-positive results released by direct-to-consumer genetic tests highlight the importance of clinical confirmation testing for appropriate patient care

Stephany Tandy-Connor, MS, Jenna Gultinan, MS, Kate Krempely, MS, Holly LaDuca, MS, Patrick Reineke, BS, Stephanie Gutierrez, BS, Phillip Gray, PhD and Brigette Tippin Davis, PhD, FACMG

**Purpose:** There is increasing demand from the public for direct-to-consumer (DTC) genetic tests, and the US Food and Drug Administration limits the type of health-related claims DTC tests can market. Some DTC companies provide raw genotyping data to customers if requested, and these raw data may include variants occurring in genes recommended by the American College of Medical Genetics and Genomics to be reported as incidental/secondary findings. The purpose of this study was to review the outcome of requests for clinical confirmation of DTC results that were received by our laboratory and to analyze variant classification concordance.

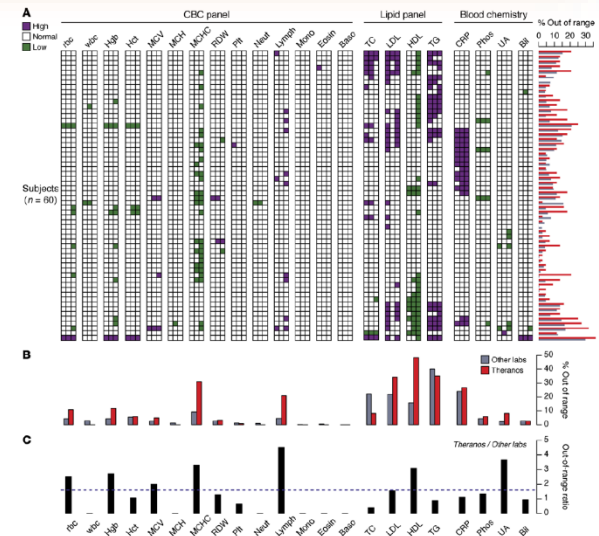
**Methods:** We identified 49 patient samples received for further testing that had previously identified genetic variants reported in DTC raw data. For each case identified, information pertaining to the outcome of clinical confirmation testing as well as classification of the DTC variant was collected and analyzed.

**Results:** Our analyses indicated that 40% of variants in a variety of genes reported in DTC raw data were false positives. In addition, some variants designated with the "increased risk" classification in DTC raw data or by a third-party interpretation service were classified as benign at Ambry Genetics as well as several other clinical laboratories, and are noted to be common variants in publicly available population frequency databases.

**Conclusion:** Our results demonstrate the importance of confirming DTC raw data variants in a clinical laboratory that is well versed in both complex variant detection and classification.

*Genet Med* advance online publication 22 March 2018

**Key Words:** classification discrepancy; clinical confirmation direct-to-consumer; false positive; raw data



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

CUSTOMER REVIEWS

Don't take our word for it...



"I'm always intrigued by what I find on 23andMe each time I log in. I've learned so much about my health, ancestry, and specific genes that I have mutations for that I'm currently getting medical care for. Find a way, get tested today!"

Gary

California, USA  
Health + Ancestry



"I got my kit in July 2018 and got my results that August and I'm so happy I did! I was able to find out some helpful health information as well! I've also been connected to a side of my family that I know little to nothing about, which has been so great being able to learn new things!"

Nat

- The **purpose** of 23andMe Research is **to make new discoveries** about genetics and other factors behind diseases and conditions.
- **If you agree to this consent**, you **allow 23andMe researchers to use certain information** (including your Genetic Information and your responses to research surveys) to study a wide variety of research topics.
- To protect your **privacy**, 23andMe conducts research with information that has been **stripped of your name and contact information** and combined with similar information from many research participants.
- Some 23andMe Research is conducted in **collaboration with third parties**, such as non-profit organizations, pharmaceutical companies, or academic institutions. **We may share summaries of research results, which do not identify any particular individual**, with qualified research collaborators and in scientific publications.
- It is unlikely that you will directly benefit from your participation, though you and others **may benefit in the future** from discoveries that lead to healthcare advances or improvements to 23andMe's product or services. **There is a very small risk** that someone could get access to your Personal Information (information that can be used to identify you) without your permission in the event of a privacy breach.

*„primum non nocere, secundum cavere, tertium sanare“*

**NOW WITH 2000+ REGIONS**  
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**Neanderthal Ancestry**  
Discover how much Neanderthal DNA you inherited.  
[Learn more](#)

## Research Consent Document

Part of 23andMe's mission is to help people benefit from the human genome, and research is an important part of that mission. Here are some highlights from our Research Consent Document. **Please read the entire consent document below before making a decision to participate.**

### Key Information:

- The **purpose** of 23andMe Research is to **make new discoveries** about genetics and other factors behind diseases and traits.
- If you **agree to this consent**, you allow **23andMe researchers to use certain information** (including your Genetic Information and your responses to research surveys) to study a wide variety of research topics.
- To protect your **privacy**, 23andMe conducts research with information that has been **stripped of your name and contact information** and combined with similar information from many research participants.
- Some 23andMe Research is conducted in **collaboration with third parties**, such as non-profit organizations, pharmaceutical companies, or academic institutions. **We may share summaries of research results, which do not identify any particular individual**, with qualified research collaborators and in scientific publications.
- It is unlikely that you will directly benefit from your participation, though you and others may benefit in the future from discoveries that lead to healthcare advances or improvements to 23andMe's product or services. **There is a very small risk** that someone could get access to your Personal Information (information that can be used to identify you) without your permission in the event of a privacy breach.
- Taking part in this research is **completely voluntary**, and you can **change your consent choice at any time** without affecting your access to the 23andMe product or services.

### Purpose: Why is 23andMe doing research?

23andMe Research aims to make and support scientific discoveries about genetics and other factors behind diseases and traits. To do this, we conduct our own research and support the work of other researchers around the world by **collaborating and publishing our findings** in scientific journals. Results of our research may be used to help develop **new ways to diagnose and treat disease**, or **new reports and features** for the 23andMe product or services. We study:

- The genetic and other factors behind diseases and traits
- Ways to diagnose and treat diseases
- The history of peoples across the world, including how they migrated and intermixed in the past
- How people react to learning about their genetics

Topics include simple traits such as hair color or freckles, serious diseases such as Parkinson's disease or diabetes, and less serious conditions such as migraine headaches.

23andMe makes discoveries by analyzing information across large numbers of research participants to find patterns. These patterns might tell us, for instance, if people with a particular set of genetic factors are more likely to get a disease such as cancer or asthma. Another pattern might point to a new way to treat a disease. **Results of our research may be used to help develop new drugs.** Some discoveries made by 23andMe could help researchers **better understand disease** and may guide diagnosis and treatment decisions.


For example, in 2020 23andMe conducted a study of genetic factors that contribute to susceptibility to COVID-19. We found that the ABC blood groups lead to differences in severity of the disease.

Other discoveries help us understand the **history of human migrations** that led to our current world populations.

For example, in 2020 23andMe shared their findings about the genetic impact of the Transatlantic Slave Trade on people in the Americas. We found that the genetic data concealed closely with the historical records of people being forcibly transported from Africa, but there were notable exceptions of discrepancies that shed light on this important period in history.

### What does it mean to take part in 23andMe Research?

If you choose to take part in 23andMe Research, you will be asked to take surveys or enter information about yourself into the 23andMe website or mobile app. You **choose which surveys to take**, which information to **provide**, and **which questions to answer**. Giving consent means that you agree to let 23andMe researchers use your **Genetic and Self-Reported Information** (including such information provided prior to giving consent) for 23andMe Research. **"Genetic and Self-Reported Information"** includes:

- Your genetic data
- Information you enter into the website or mobile app that is labeled with the 23andMe Research logo 
- Your age and ethnicity
- Data from a third party that you authorize us to use for research
- **23andMe Research is open-ended**—we may inform you of new surveys and research opportunities as they are added. We may also invite you to participate in specific studies based on information you've previously provided. We use routine communication methods to inform you of research opportunities. We may send you email invites and/or notifications in your account or on your mobile device.
- When 23andMe conducts studies on sensitive research topics, you will be provided additional information to help you decide whether you want to take part in this research.
- Depending on the research activity, we may or may not provide you with compensation for your time. For some longer or more involved research activities, cash equivalents, or charitable donations may be provided as compensation. **There is no cost to take part in this research.**
- Some 23andMe Research may be **sponsored by or conducted in collaboration with third parties**, such as non-profit organizations, pharmaceutical companies, or academic institutions whose additional expertise and/or resources can help 23andMe make important discoveries.
- Sometimes research discoveries lead to products or inventions that have value if they are made or sold. In situations where your information contributed to an invention or product that profited 23andMe or any of its research collaborators, you will not receive any financial benefits.
- If you have elected to have your saliva sample stored by 23andMe, we may also use the results of further analysis of your sample in 23andMe Research. For example, we may **conduct whole genome sequencing** which allows researchers to study

authorizes 23andMe to use their Genetic and you discuss 23andMe Research with your child.

\*You can learn more about Genetic Information, Information in our Privacy Statement.

### How is my privacy protected?

**23andMe uses physical, technical, and admin** and improve our privacy and security practices to limit access to the following:

• 23andMe research analyses are conducted with **Information** (information you provide when your contact information may be used to contact you) Reported Information.

• When we publish research results or share results, we **do not identify any particular individual** and 23andMe maintains an **internationally recognized** security systems.

• All 23andMe employees are trained on how to conduct research additional training on how to conduct research.

### Who will have access to my information?

Outside of 23andMe:

- We may share **summaries of research** research collaborators and in scientific publications.
- We may share information with our **ethics** agencies to maintain our compliance, or:
- Within 23andMe:
  - 23andMe researchers who conduct analyzing Identifying Registration Information.
  - For further details on 23andMe's other us

### What are the benefits and risks of taking part?

- You will not receive any direct benefits by taking results about your genetics or health risks to you:
  - Sometimes in the future, you or others, may indirectly from 23andMe Research discover contributing ways to prevent and treat diseases.
  - By taking surveys you may learn about 23andMe contributed to and provide you with

### Risks:

- Discomfort: Some survey questions or data or Privacy. Although 23andMe has strict policies that a breach of your Personal Information could:
  - In the event of a breach, your Genetic and 23andMe. In some cases, a breach could
  - There is a remote chance that an individual, research results. In theory, a bad actor will research results and determine that you're related to the study.
- There may be additional risks to participation

### Can I change my mind?

- Your participation in the 23andMe Research changes your mind about participating, you can withdraw your consent, 23andMe will present Research initiated after 30 days from when you:
  - You may also stop participation by closing your account within your Account Settings.
  - You may choose not to give consent to 23andMe for other purposes, such as to improve the 23andMe participation in 23andMe Research could 23andMe (described in our Privacy Statement Services).

### Who do I contact if I have questions?

1. **Aggregate Information:** Information that has been combined with that of other users and analyzed or evaluated as a whole, such as the specific individual or personally identifiable.
2. **De-identified Information:** Information that has been stripped of your Registration Information (e.g., your name and contact information) and other identifying data such that you cannot reasonably be identified as an individual, also known as pseudonymized information.
3. **Individual-level Information:** Information about a single individual's genotypes, diseases or other traits/characteristics, but which is not necessarily tied to Registration Information.
4. **Personal Information:** Information that can be used to identify you, either alone or in combination with other information. 23andMe collects and stores the following types of Personal Information:

- a. **Registration Information:** Information you provide about yourself when registering for and/or purchasing our Services (e.g., name, email, address, User ID and password, and payment information).
- b. **Genetic Information:** Information regarding your genotypes (i.e. the As, Ts, Cs, and Gs at particular locations in your genome), generated through processing of your saliva by 23andMe or by its contractors, successors, or assignees, or otherwise processed by and/or contributed to 23andMe.
- c. **Self-Reported Information:** Information you provide directly to us, either through the Services or through a third party, including your disease conditions, other health-related information, personal traits, ethnicity, family history, and other information that you enter into surveys, forms, or features while signed in to your 23andMe account.
- d. **Sensitive Information:** Information about your health, Genetic Information, and certain Self-Reported Information such as racial and ethnic origin, sexual orientation, and political affiliation.

- e. **User Content:** Information, data, text, software, music, audio, photographs, graphics, video, messages, or other materials - other than Genetic Information and Self-Reported Information—generated by users of 23andMe Services and transmitted, whether publicly or privately, to or through 23andMe.
- f. **Inferences and Derived Data:** Information, data, assumptions, or conclusions that are derived directly or indirectly from another source of Personal Information. For example, we may use statistical techniques to infer additional genetic information based on genetic information generated directly through the processing of your saliva sample.
- g. **Web-Behavior Information:** Information on how you use our Services collected through log files, cookies, web beacons, and similar technologies (e.g., device information (device identifiers), IP address, browser type, domain, page views).

### 2. Information we collect

#### 1. Information you provide directly to us or through a third party

**Registration Information.** When you purchase our Services or create a 23andMe account, we collect Personal Information, which may include your name, date of birth, billing and shipping address, payment information (e.g., credit card) and contact information (e.g., email, phone number and license number).

**Self-Reported Information.** You have the option to provide us with additional information about yourself through surveys, forms, features and applications. For example, you may provide us with information about your personal traits (e.g., eye color, height), ethnicity, disease conditions (e.g., Type 2 Diabetes), other health-related information (e.g., pulse rate, cholesterol levels, visual acuity), and family history information (e.g., information similar to the foregoing about your family members). Before you disclose information about a family member, you should make sure you have permission from the family member to do so.

**User Content.** Some of our Services allow you to create and post or upload content, such as data, text, software, music, audio, photographs, graphics, video, messages, or other materials that you create or provide to us through either a public or private transmission ("**User Content**"). For example, User Content includes any discussions, posts, or messages you send on our Forums.

**Blogs and Forums.** Our website offers publicly accessible blogs. Additionally, 23andMe customers may participate in our online Forums. You should be aware that any information you provide or post in these areas may be read, collected, and used by others who access them. To request that we remove or de-identify your Personal Information from our blog or Forums, contact us at [privacy@23andme.com](mailto:privacy@23andme.com). Please note that whenever you post something publicly, it may sometimes be impossible to remove all instances of the posted information, for example, if someone has taken a screenshot of your posting. Please exercise caution before choosing to share Personal Information publicly on our blogs, Forums or in any other posting. You may be required to register with a third party application to post a comment. To learn how our third party application uses your information, please review the third party's terms of use and privacy statements.

**Social media features and widgets.** Our Services include Social Media Features, such as the Facebook, "Like" or "Share" button and widgets ("Features"). These Features may collect your IP address, which page you are visiting on our site, and may use a cookie to enable the Feature to function properly. They may also allow third party social media services to provide us information about you, including your name, email address, and other contact information. The information we receive is dependent upon your privacy settings with the third party social media service. Features are either hosted by a third party or hosted directly on our site. Your interactions with these Features are governed by the privacy statements of the third party companies providing them. You should always review and, if necessary, adjust your privacy settings on third party websites and services before linking or connecting them to our website or service.

**Third party services (e.g., social media).** If you use a third party site, such as Facebook or Twitter, in connection with our Services to communicate with another person (e.g., to make or post referrals to or request that we communicate with another person), then in addition to the person's name and contact information, we may also collect other information (e.g., your profile picture, network, gender, username, user ID, age range, language, country, friends lists or followers) depending on your privacy settings on the third party site. We do not control the third party sites' information practices, so please review the third party's privacy statement and your settings on the third party's site carefully.

**Third party sign in.** You may create a 23andMe account and/or sign in to our Services using an account you created with a third party service, such as Google. If you provide authorization to 23andMe, we will collect and use the information you share with us via that third party service (such as your email address, name, and date of birth as specified in your third party service account) in accordance with this Privacy Statement. You are responsible for managing your credentials for your third party service account, and for maintaining the security of your third party service account. 23andMe does not have access to the credentials for your third party service account. If you choose to use third party sign in and you lose access to your credentials for your third party service account, you may not be able to access your 23andMe account. You may manage authorization for third party sign in through your 23andMe Account Settings or through your third party service account.

**Referral information and sharing.** When you refer a person to 23andMe or choose to share your 23andMe results with another person, we will ask for that person's email address. We will use their email address solely, as applicable, to make the referral or to communicate your sharing request to them, and we will let their contact know that you requested the confirmation. By participating in a referral program or by choosing to share information with another person, you confirm that the person has authorized consent for 23andMe to communicate with (e.g., via email with their email or by the person

or relations) and analyze and improve our Services.

involve of some core components of our data handling practices.

about:

**our Services.** We collect Web-Behavior Information via our website, mobile apps, products, or other information.

collect and process your information whenever you place an order, conduct research surveys, post on our Forums or use other messaging (we generally categorize as Registration Information, Self-Reported Information).

**services.** With your consent, we extract your DNA from your saliva (the As, Ts, Cs, and Gs at particular locations in your genome) in

on for the following reasons:

Personal Information in order to provide our Service, which includes creating customer accounts and activating tools, analyzing tools like DNA Relatives.

ing. We constantly work to improve and provide new reports, tools to improve our ability to assign specific ancestors to your DNA, and it also needs to fix bugs or issues, analyze the use of our website to

**consent.** If you choose to consent to participate in 23andMe Research Genetic Information and Self-Reported Information in a scientific discovery.

boot how your data is shared and used. You choose:

ngle after it has been analyzed. If or opt-in to view.

**Information.** including friends, family members, health care providers, third party services that access 23andMe data and social media. We Research. By agreeing to the Research Consent Document, if in a 23andMe Research Community you can consent to the use of

I data, at any time.

d in the following ways:

essary for them to provide their services to us. us, only if you provide your explicit consent.

Individual-level information to a third party for research purpose

**public databases.** In (genetic or non-genetic) to an insurance company or employer enforcement or regulatory authorities unless required by law or for benefit or Personal Information (visit our Transparency &

ments to ensure confidentiality, integrity, and availability of 23andMe practices to help ensure the integrity of our systems and you the following areas:

**and audit.** Our information security management system, which involves, has been certified under the internationally recognized I described below.

standard security measures to encrypt Sensitive Information but

neal. We limit access of information to authorized personnel, but we multi-factor authentication, single sign-on, and a strict least-to

ing our Services that you haven't considered.

elf and/or your family members that may be upsetting or cause a previously unknown to you, or may learn that someone who thought

### b. Information related to our genetic testing services

**i. Saliva sample and biobanking.** To use our genetic testing services, you must purchase, or receive as a gift, a 23andMe Genetic Service. Service testing kit, create an online account and register your kit, and ship your saliva sample to us or our third party laboratory. Your DNA will be extracted from your saliva sample for analysis. During kit registration you are asked to review our Consent Document for Sample Storage and Additional Genetic Analyses. Unless you consent to sample storage ("Biobanking") and additional analyses of your saliva sample and DNA are destroyed after the laboratory completes its work, subject to laboratory legal and regulatory requirements. You can update your Biobanking preference to discard a stored sample within your 23andMe Account Settings once your sample has completed processing.

**ii. Genetic Information.** Information regarding your genotype (i.e. the As, Ts, Cs, and Gs at particular locations in your genome), your Genetic Information, is generated when we analyze and process your saliva sample, or when you otherwise contribute or access your Genetic Information through our Services. Genetic Information includes the 23andMe results reported to you as part of our Services, and may be used for other purposes, as outlined in Section 3 below.

**c. Web-Behavior Information collected through tracking technology (e.g. from cookies and similar technologies)** We and our third party service providers use cookies and similar technologies (such as web beacons, tags, scripts and device identifiers) to:

- i. help us recognize you when you use our Services;
  - ii. customize and improve your experience;
  - iii. provide security;
  - iv. analyze usage of our Services (such as to analyze your interactions with the results, reports, and other features of the Service);
  - v. gather demographic information about our user base;
  - vi. offer our Services to you;
  - vii. monitor the success of marketing programs; and
  - viii. serve targeted advertising on our site and on other sites around the Internet.
- If you reject cookies, you may still use our site, but your ability to use some features or areas of our site may be limited. For more information, including the types of cookies found on 23andMe and how to control cookies, please read our Cookie Policy.

We may receive reports based on the use of these technologies from third party service providers as de-identified. Individual-level information or aggregate information (as described in Section 4.c.)

**Google Analytics.** Google Analytics is used to perform many of the tasks listed above. We use the User-ID feature of Google Analytics to combine behavioral information across devices and sessions (including authenticated and unauthenticated sessions). We have enabled the following Google Analytics Advertising features: Remarketing, Google Display Network Impression Reporting, Google Analytics Demographics and Interest Reporting, and DoubleClick Campaign Manager Integration. We do not merge information collected through any Google advertising product with individual-level information collected through our Services. **Learn more about how we use Google Analytics and use data here.** To opt out of Google Analytics Advertising Features please use Google Ad Settings. To opt out of Google Analytics entirely please use this link.

**D. Other Types of Information** We continuously work to enhance our Services with new products, applications and features that may result in the collection of new and different types of information. We will update our Privacy Statement and/or obtain your prior consent to new processing, as needed.

**3. How we use your information** 23andMe will use and share your information with third parties only in the ways that are described in this Privacy Statement.

**A. To provide you with Services and to analyze and improve our Services** We use the information described above in Section 2 to plan, create, provide, analyze and improve our Services. These activities may include, among other things, using your information in a manner consistent with this Privacy Statement to:

- i. open your account, enable purchases and process payments, communicate with you, and implement your requests (e.g., referrals);
- ii. enable and enhance your use of our website and mobile application(s), including authenticating your visits, providing personalized content and information, and tracking your usage of our Services;
- iii. contact you about your account, and any relevant information about our Services (e.g. policy changes, security updates or issues, etc.);
- iv. enforce our Terms of Service and other agreements;
- v. monitor, detect, investigate and prevent prohibited or illegal behaviors on our Services; to combat spam and other security risks; and
- vi. perform research & development activities, which may include, for example, conducting data analysis in order to develop new or improve existing products and services, and performing quality control activities.

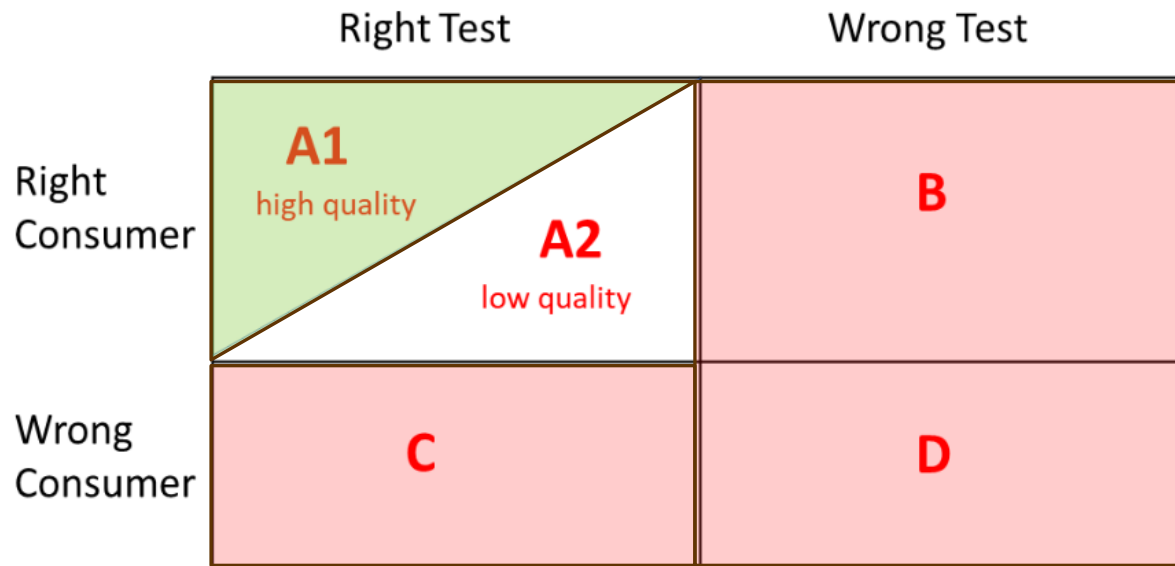
For individuals located in the European Economic Area ("EEA"), United Kingdom, or Switzerland (collectively the "Designated Countries") we process your Personal Information in this way to provide our Services to you in accordance with our Terms of Service.

**B. To process, analyze and deliver your genetic testing results** As described above, to receive results through the Personal Genetic Service, you must create a 23andMe account, register your kit, and submit your saliva sample to be genotyped by us or our contractual laboratory. Once genotyped, we further analyze your Genetic Information to provide you with our health and/or ancestry reports, depending on the Service purchased. 23andMe continuously works to improve our Services based on our research and product development, and genetic associations identified in scientific literature. If you are eligible to receive additional reports or updates in the future, you may be notified or it may directly access these updates.

For individuals located in the Designated Countries: Our legal basis for processing your Sensitive Information for the purposes described above is based on your consent. You may withdraw your consent at any time by deleting your Account via your 23andMe Account Settings; however, the withdrawal of your consent will not affect the lawfulness of processing based on consent before its withdrawal.

**C. To allow you to share your Personal Information with others** You are granted the ability to share your Personal Information, including Personal Information through the Services. You have the option to share directly with individuals with 23andMe accounts through (i) our Forums, (ii) relate findings (e.g.,

# Proposal for DTCT rating



<p><b>A1: Right consumer, right test; high quality test</b> <b>(ACCEPTABLE)</b></p>	<p>Consumer has symptoms or risk factors and chooses the correct test</p> <p>test is high quality</p> <p>results lead to clinical follow-up &amp; treatment</p>	<p>Consumer is symptomatic and wants to exclude SARS CoV2 infection</p> <p>Positive test is confirmed by RT-PCR</p>	<p>Benefits the healthcare system facilitates consumers to seek medical attention</p> <p>reduces clinical visits when correctly tested negative</p>
<p><b>A2 Right consumer, right test; low quality test</b> <b>(ACCEPTABLE ONLY IN CERTAIN CIRCUMSTANCES)</b></p>	<p>The consumer has symptoms or risk factors and chooses the correct test. The test is low quality.</p>	<p>Consumer in high HIV prevalence setting (resource-poor setting)</p>	<p>Benefits of correct test results might outweigh the harms by false positives and false negatives</p>

<p><b>B: Right consumer, wrong test</b> <b>(NOT ACCEPTABLE)</b></p>	<p>Consumer has symptoms or risk factors for a condition, but chooses wrong test</p>	<p>Symptoms of blood in the urine. Chooses a test for chlamydia, but the infection actually is UTI. They receive a true negative result for chlamydia; does not treat UTI. Delayed treatment of UTI</p>	<p>Consumers are harmed when healthcare decisions are misled by wrong tests and wrong information</p>
<p><b>C: Right test, wrong consumer</b> <b>(NOT ACCEPTABLE)</b></p>	<p>test is good test if used appropriately in clinical setting for certain patients, but not when marketed widely and indiscriminately</p>	<p>AMH testing (appropriate as part of clinician facilitated fertility treatment) is sold to young women as 'egg timer' to measure ovarian reserve</p>	<p>Unnecessary and inappropriate tests lead to information that do not lead to clinically useful decisions. Test is a wasteful use of resources</p> <p>Consumers may be harmed if the test results lead them to take unnecessary treatments</p>

<b>D: Wrong test, wrong consumer</b>  <b>(NOT ACCEPTABLE)</b>	<b>Non-evidence based tests (bogus) tests</b>	<b>Consumer choose a DTCT 'sink test'. The results lead them to use a remedy that does not effectively treat their symptoms. They are still not correctly diagnosed</b>  <b>Consumer is healthy. They choose a 'food sensitivity test' using IgG4. The results lead them to an elimination diet where important food groups are cut out and leads to malnutrition/social deprivation</b>	<b>Consumers are harmed in both the testing and in the treatment when they use non-evidence based tests</b>
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# Conclusions:

1. Define DTCT – decide between serious and bogus laboratory tests
2. **Use DTCT only for healthcare decisions when appropriate (“intended purpose” – do not mix with “intended use”)**
3. Keep healthcare data and recreational testing data separate
4. Know the consequences of “bad test quality” / overmedicalization
5. Genetic tests in DTCT is a no go
5. No test result is preferred over a wrong test result