Opinion Paper

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Direct-to-consumer laboratory testing (DTCT): challenges and implications for specialists in laboratory medicine

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Abstract: *In vitro* diagnostics (IVD) testing is a powerful tool for medical diagnosis, and patients‘ safety is guaranteed by a complex system of personnel qualification of the specialist in laboratory medicine, of process control, and legal restrictions in healthcare, most of them under national regulation. Direct-to-consumer laboratory testing (DTCT) is testing ordered by the consumer and performed either by the consumer at home or analysis of self-collected samples in a laboratory. However, since DTCT are not always subject to effective competent authority oversight, DTCT may pose risks to lay persons using and relying on it for healthcare decision-making. Laboratory medicine specialists should be very cautious when new DTCTs are introduced. As qualified professionals, they should feel obliged to warn and educate patients and the public about the risks of inappropriate and harmful DTCT.

Keywords: direct-to-consumer testing; *in vitro* diagnostics; laboratory medicine; medical device regulation.

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Introduction

The digital revolution of self-measurement and self-quantification [1] attempts to accelerate the use of scientific and technological breakthroughs [2], and serves as a trigger for the use of direct-to-consumer testing (DTCT). The difference between traditional testing and this new development is who is requesting the tests. In this paper, we will use the term DTCT for testing ordered by a lay person and performed either by the consumer at home or for testing with self-collection of the samples and analysis in a laboratory (self-sampling). We will not comment in detail on direct access testing (DAT), which is essentially identical to regular laboratory testing except that a lay person requests the test (Figure 1). For different definitions and regulations of DTCT in some countries see Table 1.

Self-empowerment of patients (“P4-medicine”) [3] and the business opportunities of homebased sampling question the traditional organization of laboratory medicine. Numerous claims suggest to consumers that increased health data collection and subsequent analysis may fundamentally improve the ability for an individual to understand and predict the state of her or his health, and that DTCT will even generate beneficial and actionable medical information [4]. Examples of DTCT are given in Table 2. Other drivers of DTCT are the alleged lack of capacity of medical laboratories in some special situations such as high-demands during the COVID-19 pandemic, and making the test more readily available since the person will not see the doctor due to the stigma and fear of discrimination associated with certain tests, such as by sexually-transmitted diseases (STD) and HIV testing, when this testing is performed in medical laboratories [5].

The very high number of laboratory tests performed worldwide together with the well-known medical benefits of *in vitro* testing [6] are strong arguments for many lay persons to access IVD tests, either performed in medical laboratories (either ordered by healthcare professionals or as DAT or as DTCT (Figure 1). Given the extensive variety of IVD available as DTCT, the numerous measuring systems

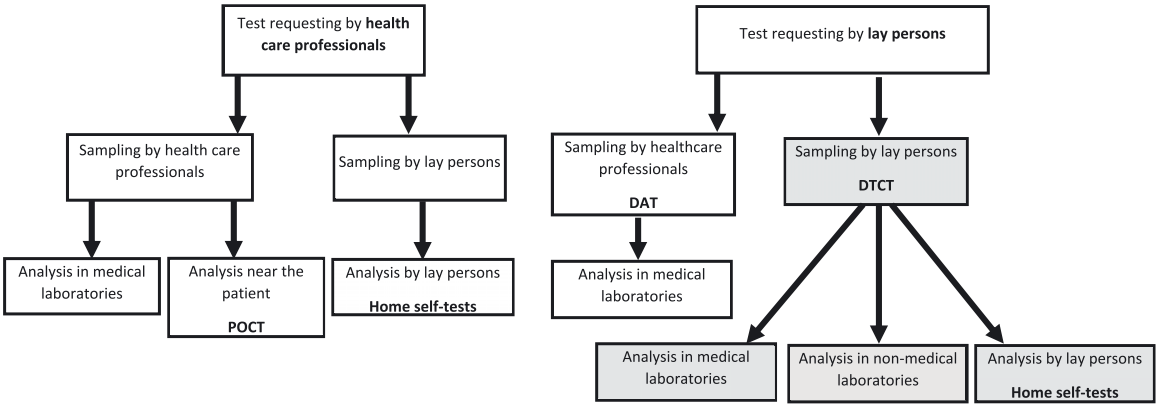

Figure 1: Options for laboratory test requesting, sampling and analyzing by health care professionals and by lay persons. Analysis by direct-to-consumer testing (DTCT) as described in this paper is marked in gray.

Table 1: Different definitions and national regulations of DTCT.

USA	IVDs that are marketed directly to consumers without the involvement of a health care provider are called **DTC**. These tests generally request the consumer to collect a specimen, such as saliva or urine, and send it to the company for testing and analysis (https://Fda.gov). **Nongenetic DTCT** has a variety of models, including OTC home test kits or drop-in clinics or pharmacies, where blood tests are offered directly to consumers without requiring a physician requisition. The test menu available to consumers encompasses much of the clinical laboratory test menu. Frequently tests are offered as packages to assess "wellness" or "metabolic health" and include a variety of hormones, vitamins, trace metals, or other tests. The steps in this model of testing closely mimic the total testing process of conventional clinical laboratories. Because of this similarity, the challenges and opportunities for error are comparable. However, under the veil of nondiagnostic, wellness, testing outside of a clinical laboratory improvement Amendments-regulated laboratory, the requirements for quality assurance are reduced, or altogether nonexistent [37]
Germany	**DTCT** is initiated directly by the patient and is under the sole responsibility of the patient in terms of performance and interpretation. DTCT can be performed either as an over-the-counter test kit (e.g. pregnancy test) or can be a sample collection kit with a voucher for biochemical, quacksalver, or genetic testing in a commercial laboratory which can be purchased on the internet, in drugstores or pharmacies [38]
Australia	**DTC home self-tests:** *In-vitro* diagnostic devices (IVDs) used by a lay person; immediate and direct results; results interpreted by the lay person. Any consumer can directly purchase and use self-tests for home use if the product is registered with the Australia Registry of Therapeutic Goods (ARTG). However, tests for serious diseases are excluded from being supplied under the therapeutic goods (excluded purposes) specification 2010. Reviews of the specification in 2014 and 2020 have since revoked the exclusion of HIV and other serious conditions (including selected STIs, cardiovascular diseases (CVD), diabetes, liver and kidney diseases), enabling tests for these conditions to be supplied as DTC home self-tests. The 2020 review continued the exclusion of tests for cancers and human genetics from being supplied as DTC home self-tests [39]

Table 2: Examples of tests offered as DTCT.

Good tests that are potentially useful when used appropriately[a] (tests appropriate for use as DTCT by consumers because it is likely to be accurate and create benefit when used without clinician guidance)	– Home pregnancy test – Capillary Lactate testing – SARS CoV-2 testing in symptomatic people
Good test used inappropriately (tests that would normally be used appropriately in a laboratory for a specific purpose, but is being sold for a different purpose as DTC test, therefore more likely to be misused by consumers)	– HIV rapid test[b] – Capillary vitamin D testing – SARS CoV-2 testing in asymptomatic people
Test with no scientific validity (tests with no scientific validity and therefore will likely mislead and harm consumers who use it without adequate information, or clinician guidance	– Hair analysis for nutrition deficiencies by quantum response technology – Multiple IgG4 testing for food allergies – Liver detoxification test – Targeted amino acid therapy addressing neurotransmitter and hormone imbalances

[a]These tests can be used in the grayzone of "restricted clinical use POCT" instead of being a DTCT only. The classification of a certain test might depend on the setting used (e.g., [b]HIV rapid tests detecting antibodies are very beneficial in high incidence conditions but are not suited to detect recent infections in low incidence settings [40]).

used for these tests, and the ability for consumers to access products across national boundaries via the internet, DTCT presents a significant business opportunity for the vendors, challenging many regulations of healthcare [7].

Unlike other medical professions with direct patient contact, safeguarding the patient from quackery or user errors that may affect test results *in vitro* testing is very challenging. Obvious misleading and fraudulent products or services, such as "sink testing" [8], the infamous Theranos story [9], or, very recently, the spending in Germany of >1 billion € for SARS-CoV-2 rapid tests which were billed but had not been performed properly [10], indicate the ease of misleading practices in IVD testing and the potential harm to patients, consumers, and the society as a whole.

Regulatory challenges

The provision of IVD testing services is generally seen as the provision of healthcare. Healthcare is regulated on a national level and is different even in each member state of the European Union [11]. Article 168 [3] of the Treaty on Functioning of the European Union allows the EU to regulate IVD tests as such but leaves little scope for regulating the provision of testing services at EU level. European law regulates IVD devices for self-testing (patient applies the test and interprets the text by him/herself) and devices for self-sampling by a patient and for transport of specimens to a testing laboratory, but does not regulate the testing service as such. Therefore, legal regulations for IVD testing services differ substantially between national health systems which make it challenging to describe standards for a universal strategy necessary to protect the patients and the consumers. In general, patients' healthcare is guaranteed by a complex structure that e.g. regulates the qualification of the personnel (such as minimum standards for training and continuous education of laboratory medicine specialists), the quality of a laboratory by the government and/or accreditation agencies (including worker protection, safeguarding the environment, and for infection control), and ongoing monitoring of performance quality by internal quality control and external quality assessment such as regulated national agencies (Tables 3, 4). The measuring systems (such as test kits, instruments and testing devices) allowed on the market are regulated by EU legislation (IVDR) [12] subject to a market access process called "CE-marking". CE-marking relies partially on self-certification and partially on certification by independent external certification bodies (called 'notified bodies'), with national authorities responsible for market surveillance (following up incidents and enforcing against non-compliant products). However, for laboratory testing outside of healthcare (such as for lifestyle testing), many countries essentially have no specific qualifications or formal approval to be met for testing services or for vendors of tests kits to be sold for recreational (i.e., non-medical) purpose. For lay persons, it is nearly impossible to detect misleading products such as by counterfeited or missing FDA or CE markings, in particular when test kits are obtained through the internet. Furthermore, non-evidence based and unscientific testing services (such as by "Quantum Response Technique") offered as micronutrient testing from hair [13], are accessible by consumers.

Many DTCT products will include fine print describing the testing as "for recreational purposes only", "not for diagnostic purposes" or "this testing may not be done to diagnose diseases" but still claim a clinically relevant result in that this particular DTCT may save the consumer a visit to the doctor's office or enable making important lifestyle choices. If test results resembling that of real medical tests reports are transmitted together with recommendations such as for diet supplements, this may easily be mistaken for individualized medical advice. DTCT can only issue test

Table 3: Example of formal minimum requirements to run a general medical laboratory in healthcare (left) and in DTCT (right) under the special situation under the covid pandemic. Example is given for Germany; the non-medical laboratory performs SARS-CoV-2 testing from nasal swabs by rapid testing and/or by rapid PCR.

Medical laboratory	Non-medical laboratory (government-approved SARS-CoV-2 testing)
Education at government approved university, faculty of medicine (6 years)	1 h online training
Formal state examination	None
Licensing (approbation)	None
Member of physician chamber	None
Certification of fitness (health, criminal record)	None
Formal postgraduate laboratory medicine training (6 years)	None
Physical location of the laboratory	Valid banking account number
Appropriate liability insurance, occupational health and safety, patient data protection, patient data security	None
Quality system (RiliBAeK/ISO 15189)	None
Proof of internal quality control (IQC) and external quality assessment EQA)	None
Use of CE-marked reagents only (except for LDT testing), with independent approval by notified body	Use of class D IVDR test kits with no independent approval (only self-declaration of the vendor)

Table 4: Definition of healthcare. In essentially all countries, healthcare is restricted to registered and licensed physicians. The definition of healthcare is rather universal, but slight differences are present between different countries. Laboratory will always be regarded healthcare because of [1, 3, 8].

Healthcare encompasses
1. The diagnoses of illnesses
2. The prescription of diagnostic examinations
3. The use of invasive and/or risky diagnostic techniques
4. The determination of medical treatment
5. The prescription of medications
6. The clinical monitoring of patients
7. Giving pregnancy care and deliveries
8. Decision about isolation measures in contagious diseases

results without medical interpretation since test reports can only be issued by physicians [14].

Advertisement of these tests can suggest that a real medical test is requested and billed, while only the disclaimers in the fine print will reflect that the DTCT performed is by no means suitable for medical purposes. The unsuitability of a certain test can range from using of an otherwise appropriate test for an intended use beyond the specifications of the device (such as using certain capillary glucose strips for diabetes diagnosis [15]) up to employing outright quackery, non-scientific tests and allegedly quantitate biomarkers.

In general, advertisements for healthcare services are highly regulated and restricted by national laws, to protect the patients [16]. However, targeting the consumers directly is attractive to increase the demand (and the revenue) for these services. Furthermore, current international trade agreements challenge these restrictive national healthcare regulations [17]. The legal and regulatory challenges are even more complex in genetic DTCT since not only the consumer/patient but all persons directly genetically related (family) might be implicated as a consequence of the test results [18].

Analytical challenges

The selection of the DTC tests offered must be criticized: In general, frequently used and medically pivotal tests are offered by medical laboratories with very short turnaround times and, either covered by public or private insurance, for free or for low cost for the patients. Therefore, these tests are not in the focus of DTCT companies since there is little demand. Tests with extensive medical consequences (such as tumor markers or serological tests) pose the risk of obvious false diagnoses and will therefore usually not be offered as DTCT. Thus, most DTCT will test "soft" analytes where 1. A wide range of tests results can be obtained, which allows lengthy explanations to the consumer with actionable results (which look like sophisticated, tailored, individual comments but are in fact standardized comments only), 2. An array of analytes accessible to intervention by food supplements, which often justifies the vendor to offer nutritional supplements and recommend frequent repeat testing, or 3. Will ask for a costly panel testing for numerous analytes (such as testing for numerous allergen responses) [16].

Because DTCT are generally not intended for use in the clinical setting (healthcare), the target consumers are often healthy subjects, and the intention of DTCT is to access new markets and generate profits. The side effect is to medicalize otherwise healthy persons, starting with the idea of optimization of health and continuing with prevention and screening for overt diseases [19]. Demand for these tests is driven by, for example, showcasing certain tests via social media and influencers (e.g. standard tests such as ferritin tests are celebrated as being very precious tests and offered in an "Apple shop-like setting" [20] or by participative commenting of the test results by "peers" (i.e. other persons commenting via social media on the individual test results), which receive a discount for this comment on their own test results (much like a "Ponzi scheme" [21]). This peer commenting is named swarm intelligence but might also be generated by troll farms or by irresponsible lay persons. This medical advice generated by anonymous or obscure internet sources is very hard to enforce against by the authorities because of the often cross-border nature of the business. While medical advice by lay persons is illegal, the rating of a test kit or of a service voucher in an internet shop is common and might mislead the potential buyers. There is also a high chance that testing produces no benefit but only medical, psychological, and economic harm to the users of the tests and can be a burden to the healthcare system as a whole, in particular with follow-up testing in medical laboratories triggered by unnecessary false-positive DTCTs [19, 22]. In the concept of medical commons, the resources of healthcare are limited and therefore it is the responsibility of the healthcare professionals to respect the needs of the health care system as a whole and to use the resources with caution [23].

Laboratory setting

In medical laboratories, specialists in laboratory must use suitable tests and which are validated for medical use only

[14]. For DTCT consumers can only rely on claims and instructions of the vendors of the tests. IVD testing might look simple but in fact we are also dealing with the well-known brain-to-brain loop in DTCT [24].The whole testing process is even more complicated since consumers have no training in specimen sampling and performing the test, they are challenged by understanding the intended use of a test, have limited knowledge of medical terminology, and concerns about the billing process (since this is not covered by their insurance) and questions regarding data security and safety are not readily answered. Taken together, the process of ordering a test is fraught with complexity, and the lack of clear and compliant information makes it challenging for the consumer to make genuinely informed decisions. Since most of these tests are not for medical use, the barriers ensuring patient safety in healthcare will not protect the consumers sufficiently in most countries.

In medical laboratories, specialists in laboratory medicine will check the performance of new tests (and of tests during their continuous use) by comparing the new test with established methods, testing samples with known test results (either real patient samples and EQA and IQC samples). However, in DTCT this comparison will not be feasible, and users will need to rely on the claims of the seller regarding valid market approval of the test.

The proportion of inappropriate use of tests has grown exponentially in the last months by self-testing for SARS-CoV-2 antigen using oral fluids [25]. There are obvious benefits for self-testing of symptomatic persons, and some countries could achieve a testing regime with self-tests (many of them as DTCT) which had clear benefits to the public. But while these tests were developed and approved for testing of symptomatic patients by healthcare professionals, in some countries the tests were in fact predominantly used for testing asymptomatic patients and performed by lay persons. Furthermore, the validity of a (negative) test result (24 h) was extended to 48 h by e.g., the German government. This does not correspond with the intended use of these tests and is not supported by the testing performance characteristics. The performance of most of these tests in asymptomatic persons, even when performed by professionals under optimum conditions, was far poorer than the minimum standards required [26, 27]. This leads to the paradoxical situation that a test kit – obviously unsuited for this purpose – is misused, in some cases by direct order of the government, when the testing is performed by lay persons, while – correctly – the identical test kit might not be used by specialists in laboratory medicine for the same purpose – they must use suitable test kits only [14].

Another challenging aspect is the connection of the test results to the patient that the sample was purposedly obtained from. The mix-up of patient samples is still a major target of improvement [28] and several technological advancements (such as barcoded wristbands or double identification of the patient during blood drawing) are used frequently in medical laboratories. When samples are obtained by an alternative way such as by homebased sampling, the origin of the sample and the chain of custody is impossible to prove which makes all data registries containing such laboratory data questionable [29]. Manipulation of data is easy (i.e., fabricating [8] or deleting of test results), and the current legal framework (which sanctions the medics if they manipulate testing results or do not provide sufficient health data integrity) is not sufficient to avoid or sanction these manipulations when these are performed by lay persons. With the widespread use of long-term electronic data records, the practical use of these data records will be challenged when essentially all the data contained in these records are not connected reliably to the patient in question. The ownership and purpose of these health records are still under discussion, and the integrity and patients' benefits of these records is of particular concern in IVD data due to the large number of data and the heterogeneity of their origin (such as from POCT, continuous glucose monitoring (CGM), medical laboratories, fitness trackers, quackery laboratories) [29, 30].

Implication of DTC for specialists in laboratory medicine

Despite the fact that many DTCT tests will produce a numeric result, consumers are less likely to be interested in these, but instead requests an answer to possible personal consequences of the test, which would be the medical interpretation of the results. However, this medical interpretation moves DTCT into the realm of medicine, rather than 'lifestyle', and providers of DTCT therefore use foggy descriptions to blur the consumers of the intended purpose of DTCT. It is noteworthy that many DTCT offers were modified or even removed from the market when the vendors of these tests were confronted to prove their medical claims [16]. Typically, the advertisements of the testing contain a "not for medical use" disclaimer but the personal experiences of individuals state an improvement of the personal health by this testing, often supported by testimonies given by influencers on social media. Replies to social media comments from healthcare professionals, however, are nearly impossible since healthcare professionals are legally generally not allowed to comment in

the public on individual patients due to patient data protection issues [31], which can bias the information about DTCT in social media substantially [32, 33].

There is a substantial risk that the inappropriate use of DTCT will impact the trustworthiness of the IVD testing as a whole. Both inappropriate testing, wrong interpretation of test results, and fraudulent invoicing of DTCT will have an impact on the public trust of IVD testing, irrespective of the setting this testing is performed, and will therefore have major implications on the future work of specialists in laboratory medicine.

Specialists in laboratory medicine should best use established media channels such as newspapers or radio or television interviews to educate and train the public in using and avoiding certain IVD tests [31] (Table 5). Health literacy of the public has to be improved [34, 35] and educational efforts should be evidence-driven and performed by (health) politicians, school education, patient groups, and respective medical experts. As end-users of the products, consumers need to be involved in developing resources that would support them in making informed and appropriate purchasing and testing decisions for DTCT.

An ongoing challenge is the often-inappropriate supervision of *in vitro* testing by the national authorities. Given the limited resources of the authorities, a risk-driven approach [36] might be beneficial if complete supervision on a regular basis cannot be achieved. In many countries, national authorities focus on high volume laboratories even though these medical laboratories are well equipped in regard to personal qualification and instruments and having established a functioning quality management system. Specialists in laboratory medicine could perform risk analyses and inform and counsel their national authorities about areas of improvements, irrespective of the kind of IVD testing performed (real laboratory tests, DAT, POCT, DTCT). Unfortunately, the DTCT tests that are non-compliant are often offered online and mostly cross-border, making enforcement complicated and not cost effective in a risk-based approach.

Table 5: Manifesto to improve the safety of consumers using DTCT by active participation and intervention (when needed) of specialists in laboratory medicine.

– Be visible (in radio, newspapers, TV)
– Be proud of your achievements
– Know the medical value of medical laboratory testing
– Speak up – we are the experts of been precise
– You are the specialist in laboratory medicine – you have to be in charge fighting against quacksalvers

Conclusions

Specialists in laboratory medicine are by year-long training and extensive experience the persons who are best qualified to comment on the use of IVD tests, irrespective of the setting in which these tests are performed (such as in medical laboratories, as DAT, as POCT, as self-testing, or as DTCT). Specialists in laboratory medicine must raise their voice if inappropriate use of laboratory tests is observed and have to inform the public, competent authorities and the politicians about the risks and the absence of benefits of inappropriate IVD testing. There should be effective enforcement mechanisms for removing such tests from the market.

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