Opinion Paper

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Direct-to-consumer testing as consumer initiated testing: compromises to the testing process and opportunities for quality improvement

An opinion paper from the EFLM DTCT-Taskforce

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Abstract: Direct-to-consumer testing (DTCT) refers to commercial laboratory tests initiated by laypersons without the involvement of healthcare professionals. As this market grows in size and variety of products, a clear definition of DTCT to ground the conceptualization of their harms and benefits is needed. We describe how three different modalities of DTCT (home self-testing, self-sampled tests, and direct access tests) present caveats to the traditional testing process ('brain-to-brain loop'), and how this might differ between medical vs. non-medical laboratories. We make recommendations for ways to improve quality and reduce errors with respect to DTCT. The potential benefits and harms of DTCT will invariably depend on the context and situation of individual consumers and the types of tests involved. Importantly, implications for both consumers and the healthcare system should be considered, such as the effects on improving health outcomes and reducing unnecessary testing and use of clinical resources. 'Consumer initiation' must be a central defining characteristic of DTCT, to clearly demarcate the key drawbacks as well as opportunities of this type of testing from a laboratory specialists' perspective. The concept of 'consumer initiated testing' should also help define DTCT regulation, and provide a locus of efforts to support consumers as the main decision-makers in the purchasing and conducting of these tests in the absence of clinician gatekeeping.

Keywords: direct-to-consumer testing; consumer initiated testing; total testing process; medical overuse; *In Vitro* Devices Regulation

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Background

Direct-to-consumer testing (DTCT) refers to commercially sold laboratory tests initiated by laypersons without the involvement of healthcare professionals [1]. Unlike in a traditional clinical setting, consumers, who are not necessarily patients, can test without first having a clinical consultation. Apart from home self-testing kits performed entirely by the layperson, laboratory tests are also available as DTCT modalities – either as 'self-sampled tests' where samples are 'mailed in' for laboratory analysis, or as 'direct access testing' (DAT), a test requested by the consumer, and samples collected and analyzed at a laboratory [2]. Depending on the jurisdiction, self-sampled tests and DAT may be offered by either or both medical and non-medical laboratories.

The DTCT market is expanding rapidly, growing 20 fold between 2010 and 2020 [3], and expected to worth US$6.32 billion by 2032 [4]. The most commonly cited advantage of DTCT is improving test accessibility and choice for consumers. Reducing delays, logistics, and costs associated with clinical consultation may in some cases overcome common barriers to testing [3, 5]. Emphasizing consumer choice at the test initiation stage can nevertheless overlook the complexity and quality control required in the remainder of the testing process. The all-encompassing term 'DTCT' also subsumes a large variety of testing products, glossing over the diversity in quality, testing modality, and type of laboratory involved, if any.

The rising popularity of DTCT have significant implications for laboratory specialists, who, in a traditional clinical setting, normally collaborate closely with clinicians and patients in a 'brain-to-brain loop' of communication and decision-making [6, 7]. The absence of clinicians in DTCT creates gaps in information flow. Any errors in test selection, pre-analysis, analysis, and post-analysis will eventually impact on consumers' health outcomes, which the work of laboratory specialists is implicated. So too, are concerns about overutilization of healthcare resources through confirmatory testing and downstream clinical visits [2, 8, 9].

A growing number of DTCT are now conducted in non-medical, non-accredited laboratories, which are not regulated under the same performance standards applicable to medical laboratories. To avoid regulation as medical tests, some products are described as promoting 'wellness' and a 'healthy lifestyle' despite having obvious healthcare implications. Non-evidence-based tests or tests still under research and development are also being sold directly to the public in this way [10, 11]. Poor quality assurance and the use of unproven methods can lead to misdiagnosis and further use of non-evidence based treatments. These harms will affect the overall professional standards and public trust in laboratory testing [1].

The European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) Taskforce on DTCT is set up to advise the laboratory specialist community on this topic of growing importance. This opinion paper from the taskforce aims to:

(1) Review the different DTCT modalities and identify various implications these have on the quality of the total testing process ('brain-to-brain loop')
(2) Identify ways for laboratory specialists to improve the quality use and current practices of DTCT
(3) Recommend clear definitions and dedicated regulation for DTCT to ensure consumer protection.

DTCT modalities and laboratory pathways

This section describes how different modalities of DTCT depart from the standard processes in the traditional clinical setting, and review the potential compromises these have on testing quality. In the case of self-sampled tests and DAT, further quality issues will arise if tests are processed in non-medical laboratories.

Figure 1 illustrates the 'total testing process' in the traditional clinical setting (Figure 1A), with the patient, clinician, and laboratory specialists being the three key human agents. In the so-called 'brain-to-brain loop' [6], optimal collaboration in communication and shared decision-making can contribute to reducing human and technical errors throughout the process, and ultimately enhance quality and effective care outcomes. Any steps that circumvent the loop, including substituting or omitting certain human agents or aspects of the process can leave caveats downstream [6].

DTCT introduces a fundamental circumvention to the total testing process by making consumers the sole human agent responsible for almost all decision-making in testing. Often under-recognised are the differences between the degree of circumvention among the three different modalities of DTCT.

Home self-testing (Figure 1B) is the DTCT modality with the highest degree of circumvention, with the lay person performing the test entirely by themselves at home, without laboratory grade analysis and reporting, nor involvement of either clinicians or laboratory specialists. However, there are specific regulatory requirements and more stringent assessment criteria for these devices to off-set some of these

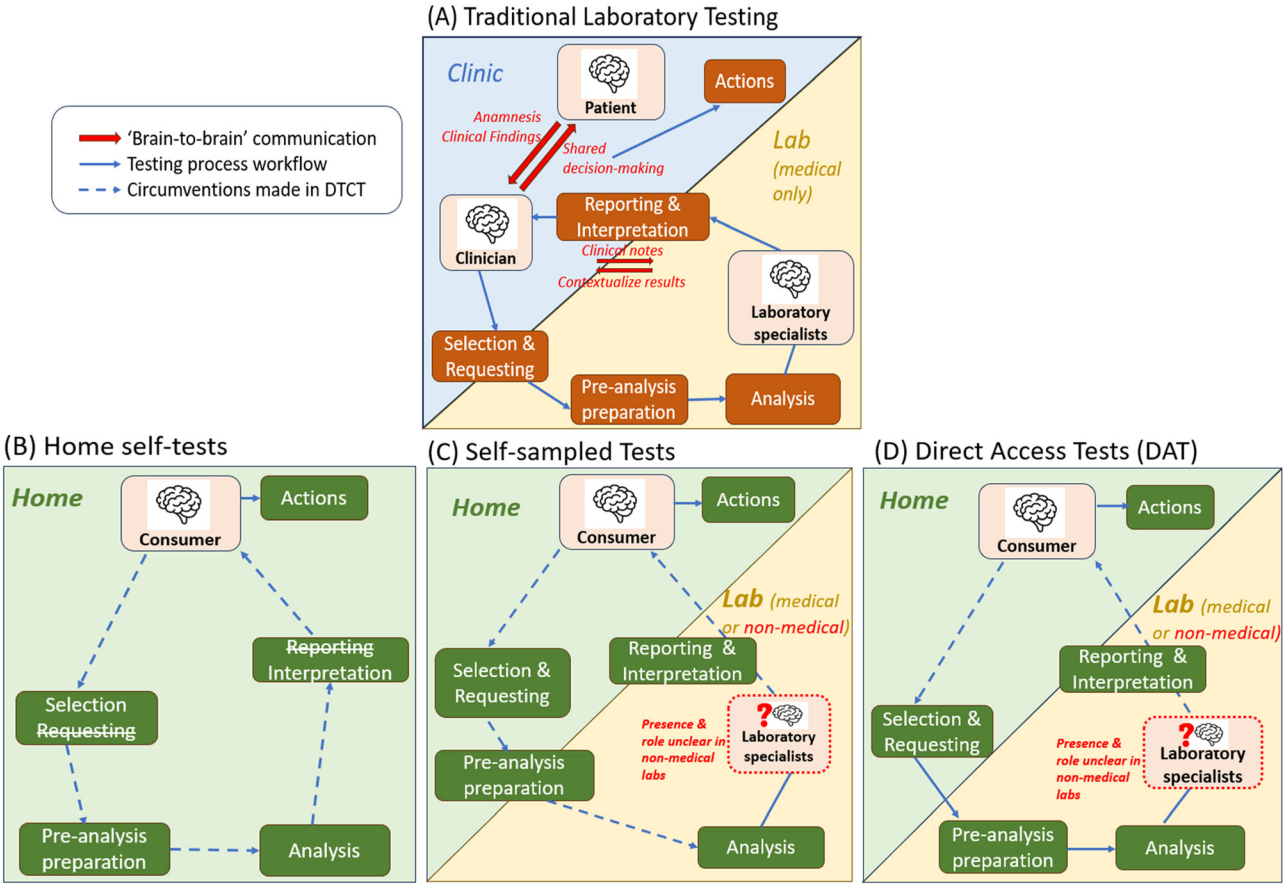

Figure 1: Brain-to-brain loop in traditional laboratory testing vs. three modalities of DTCT.

limitations. In the EU, home self-testing devices fall within *In Vitro* Devices Regulation (IVDR) (EU) 2017/746 as 'devices for self-testing with a medical intended purpose', and most are assessed as having high personal risk, with moderate to low public health risk in class C, with some exceptions in class B and D.

Both self-sampled tests (Figure 1C) and DAT (Figure 1D) enable laboratory technology for test preparation and analysis. Apart from self-sampling by consumers in Figure 1C, all other processes in these two last modalities *appear* identical to laboratory analysis in traditional clinical setting. DAT in particular, is often assumed to be the least problematic of the DTCT modalities because it presents the fewest caveats to the testing process. DTCT advertisements often reinforce the fact that tests are conducted in 'accredited' and/or 'medical laboratories' to reassure consumers. However, from the context of the 'brain-to-brain' loop, the absence of clinician guidance in test selection and requesting will nevertheless influence the potential errors in the laboratory, and therefore final actions taken by consumers.

Some jurisdictions do not allow consumers and non-medical professionals to initiate testing in medical laboratories, such as the case in Belgium and Türkiye. Some medical laboratories, especially publicly funded hospital laboratories, are restricted to requests from GPs and other registered healthcare practitioners.

However, in many other jurisdictions such as Germany, France and Sweden, DAT have existed for some time, especially as 'patient-requested testing' to enable access to tests not covered in the healthcare system, hence paid for privately. The concern in recent years though, is that this model of test initiation has become commercialised as DTCT by business arms of private medical laboratories, and driving inappropriate test initiation by consumers (who are not patients).

A further concern is the growing number of DTCT analyzed in non-medical laboratories. While medical laboratories strictly process tests for medical purposes, patient care and healthcare circumstances, this is not the case for non-medical laboratories. Hence a question mark is placed around whether there is laboratory specialist input in Figure 1C and D, in the case when samples are processed in non-medical

labs. For self-sampling devices (specimen receptacles) with a medical purpose, the manufacturer can obtain class A CE-IVDR label through self-certification. However, devices without a clearly defined medical purpose can bypass IVDR, and which have less stringent requirements for analytical and clinical performance studies [12]. Observably, some DTCT that are processed in non-medical laboratories claim to be 'ISO accredited'. However, this may be for ISO 17025 or ISO 9001 only, which are not the same high standard required of ISO 15189 accredited medical laboratories.

Circumventing the total testing process: potential benefits and harms of DTCT

The different modalities of DTCT and the type of laboratory used will have different circumventions of the total testing process. These come with both potential benefits and harms, which are broadly compared in Table 1 and discussed in this section.

Table 1: Potential benefits and risks of DTCT modalities in the testing process.

Stage in testing			Home self-testing kits	Self-sampled laboratory testing	Direct access testing
Test selection & requesting	**Potential benefits**	Timely access to testing	✓	✓	✓
		More choice in test selection	✓	✓	✓
		Reduce cost and omit logistics of clinical visits	✓	✓	✓
		Improve testing access for undertested conditions and/or under-served communities, e.g. due to social stigma or geographic distance	✓	✓	✓
	Potential risks	No clinicians to support decision-making; appropriateness of test selection less guaranteed	✓	✓	✓
		Decision-making may be influenced by commercial marketing rather than medical justifications	✓	✓	✓
Pre-analysis preparation	**Potential benefits**	Timeliness of analysis following sample collection	✓	✗	✗
		Convenience and privacy of performing sampling at home	✓	✓	✗
	Potential risks	Lay person sample collection has higher risk for human errors (e.g. injury, poor sanitation)	✓	✓	✗
		Mailed-in samples have higher risks for mislabelling & misidentification of samples	✗	✓	✗
		Sampling not performed in controlled laboratory environment (e.g. temperature, sanitation)	✓	✓	✗
		Quality assurance less consistent if pre-analysis performed in a non-laboratory environment (e.g. home) or at a non-medical, non-accredited lab	✓	✓	✓
Analysis	**Potential benefits**	Consumer receives timely analysis and results following sample collection	✓	✗	✗
	Potential risks	Higher risks of errors and reduced quality if analysed by lay persons at home, or performed at a non-medical, non-accredited laboratory	✓	✓	✓
Interpretation & reporting	**Potential benefits**	Timeliness and immediacy of interpretation	✓	✗	✗
	Potential risks	Higher risk of human errors when lay person interprets	✓	✗	✗
		No clinical notes to support contextualization of interpretation	✓	✓	✓
		Reporting and data not delivered to clinicians, nor recorded in healthcare system records	✓	✓	✓
		No monitoring, reviewing or reporting of results	✓	✗	✗
Actions	**Potential benefits**	Timeliness of actions after receiving of results	✓	✗	✗
		Consumer has choice in terms of who and where to follow-up	✓	✓	✓
	Potential risks	Actions based on inaccurate results may harm both the individual (e.g. distress, mistreatment, false reassurance from false negatives) and the healthcare system (e.g. overutilization of services)	✓	✓	✓
		No clinicians to support decision-making therefore more risk of being mislead	✓	✓	✓

Test selection and requesting (pre-preanalysis)

In all three DTCT modalities, clinicians are absent in the initial stage of test selection and requesting. Consumers self-order tests based on market supply without clinician consultation. Although this increases consumers' access and convenience at test initiation, there are also clear drawbacks. Appropriate test selection is not guaranteed without clinician input. Normally, dialogue and assessment of symptoms and medical history determines the right diagnostic test is selected based on a patient's symptoms, medical history, and clinical findings to ensure accurate and relevant results. In the absence of clinical consultations, errors and limited knowledge in judging symptoms, risk factors, medical history, and the clinical question can compromise test selection. Most crucially, marketing of DTCT influences consumer decision-making, including inappropriate and/or unnecessary test selection. As commercial products, DTCT are often marketed aggressively and broadly to anyone willing to pay. However, advertisements can sometimes include biased or misleading information [13, 14]. Mass testing panels offered by vendors screen for multiple biomarkers, despite limited or no evidence to suggest that testing healthy consumers without diagnostic purposes leads to meaningful health outcomes [15]. Inappropriate test selection, when the pre-test probability for disease is low, increases the risk of false positives and misdiagnosis. This compromises the testing process, and become issues to be managed by laboratory specialists and the broader healthcare system in terms of further investigations. There are also environmental impacts of unnecessary and inappropriate testing and laboratory waste, which are recognised sources of carbon emission [16, 17].

Quality control in pre-analytical and analytical stage

Errors in the pre-analytical and analytical stages in the medical laboratory are minimized as improvements in reliability and robust quality management systems have evolved overtime [6, 18]. For DTCT, remote sample collection and/or rapid analysis by consumers at home (e.g. home self-testing and self-sampled laboratory tests) can in some cases provide more convenience and privacy, especially for testing conditions associated with stigma, such as sexually transmitted infections (STIs). For consumers in rural and remote areas, self-collection can overcome geographic barriers [5]. However, there will be more risk of human error and reduced quality as some or all of pre-analysis and analysis take place outside of the laboratory setting. Risks such as inaccurate handling of samples, and misinterpretation of instructions can compromise sample preparation and analysis [18]. Poor quality or expired reagents – as seen with some SARS-CoV-2 rapid antigen tests – can compromise result accuracy. Incomplete reactions or reagent evaporation can result in faint or blurred lines in the reaction zone, which may be mistaken for positive results. Proper sample collection is crucial for accurate analysis, and errors at this stage can significantly impact downstream results. For self-sampled tests, errors in labelling, packaging, transportation delays, and temperature variations can also cause testing errors. Another concern is the lack of quality management systems if DTCT (self-sampled and DAT laboratory tests) are analyzed in non-accredited, non-medical laboratories. Analysis can vary significantly in these laboratories, which often lack criteria for storage, transportation, and error reporting. Technological advances in dry blood and dried urine sampling have improved patient-centred sampling. However, in the DTCT contexts linked to non-medical labs, these methods often lack clinically validated analysis, such as the IgG test promoted as a 'food sensitivity test' and dried urine testing for hormones. This increases the risk of inaccurate results.

Interpreting results in the post-analytical stage

Towards the backend of the total testing process is reporting and interpretation of test results, which includes reference intervals, decision limits and any pertinent comments or explanatory notes such as advice and clinical significance. In the traditional clinical setting, these are technical reports prepared by laboratory specialists and designed for communicating and supporting interpretation by clinicians and other healthcare professionals, which in turn are based on clinical notes and records from clinicians. In DTCT, particularly with home self-tests, the responsibility for interpreting the results falls on the consumer, and there is no formal reporting. For self-sampled testing and DAT, the absence of clinicians at this stage may compromise laboratory specialists' ability to contextualize results in the absence of the clinical context as reported by clinicians. Without a basis for interpreting these results, risks of misinterpretation may increase. Some DTCT companies provide additional support to consumers at the post-analysis stage, such as online patient portals and post-test counselling. These services are sometimes included in the purchase fee, while others require an additional cost. Furthermore, unlike in traditional clinical settings, DTCT counsellors may

not have the required qualifications, making it unclear how the clinical context of the requested sample informs the interpretation.

Challenges in post-test support, follow-up, decision-making and actions

The crucial final step of testing is about the translation of test results into practical and actionable healthcare decisions, whether this would be for diagnosis, monitoring or management [19]. The ultimate importance of test results being 'actionable' and 'useful' lies in their core function of leading to meaningful improvements in health outcomes [6, 19]. The absence of clinicians in DTCT to collaborate with consumers in contextualizing and deliberating the test results for effective health management decisions is a significant drawback for all three modalities. Although consumers have more choice in terms of where and how to proceed with their health management from here, there is a risk of inappropriate actions based on misunderstanding of results, or results that are inaccurate or poorly interpreted. For lower-risk conditions that can be effectively self-managed at home, the risks might be minimal and may even be cost-saving for the consumer and the healthcare system. However, for more complex conditions, clinician consultations are likely needed before clinical management can begin, therefore requiring further confirmatory testing. In this case, false positive results from DTCT causes wasteful clinical resources, while false negative results can lead to false reassurance. These are examples of over-utilization of healthcare system resources, and defeat the purpose of testing without clinician guidance initially [2, 20]. More concerningly, some DTCT companies offer the sale of non-evidence based dietary supplements and advise based on the results of their own tests, or further regular subscription of testing products [10]. These non-evidence based treatments and tests may further harm patients.

Improving quality use of DTCT: what can laboratory specialists do?

Our review suggests the most significant issues for consumers occur at the start and end of the process of DTCT use, where traditional clinician-patient dialogue is absent, and where commercial interests and other sources of information may be driving test utilization. Any inappropriate test selection will affect the quality of the rest of the loop. Laboratory specialists may inadvertently become implicated in these testing errors.

Although pre-analytics and analytics are usually very robust stages of the testing process with a high level of standardization when performed in a medical laboratory, in DTCT these stages are the least transparent to consumers, especially in the case of tests analysed in non-medical laboratories. DTCT DAT and self-sampled testing highly resemble traditional clinical testing, yet lack the many check-points for quality control. These crucial attributes of testing, and the accreditation differences between medical and non-medical laboratories are seldom communicated to consumers at the point of purchase.

To improve quality in the use of DTCT, the laboratory specialist community can take action to address these shortfalls in the testing process. First, laboratory specialists should safeguard and strengthen testing processes within the traditional realm of the laboratory, and advocate for broader legislation and quality control of DTCT. Second, laboratory specialists must bring their influence into the front and back ends of the testing process by advocating for better consumer support, despite this being beyond their traditional role. By communicating the importance of quality in test selection, and requesting, pre-analytical and analytical procedures and by highlighting the need for actionable results, laboratory specialists can ensure a stronger whole-system approach to quality DTCT use. Table 2 outlines a number of quality improvement recommendations.

Clear definition and dedicated regulation

Currently DTCT is inadequately and inconsistently regulated. Without dedicated regulation, they are governed as an ancillary within different sets of frameworks. DTCT home self-testing kits are regulated with other self-tests that are healthcare professional initiated, under IVDR ((EU) 2017/746). For self-sampled testing and DAT, laboratory accreditation and regulation are focused on laboratory procedures and facilities, but not 'who' initiates the testing.

Part of the issue is the absence of a precise definition of DTCT that clearly encompasses the variety of modalities, products and testing pathways. By focusing on 'consumer initiation' as the defining characteristic of DTCT, the need to protect and support consumers as the main decision-makers in the testing process can be properly addressed. 'Consumer initiation' as the shared characteristic of all DTCT would encompasses the diverse modalities and the type of laboratory used. This would address the regulatory gap for DTCT described as 'non-medical' tests, as well as the inconsistency

Table 2: Recommendations for quality improvement of DTCT.

A clear description of symptoms, exposures, and the defined population for the test should be provided to guide consumers on test appropriateness: Defining the target population increases pre-test probability, reducing false positive results. Some current DTCT advertisements describe vague indications such as "tiredness, exhaustion, headache, stomach pain", which may be common to many people, and can lead to inappropriate test selection.
The DTCT must be proven possible to use accurately and in the optimal scenario by a lay person: To reduce pre-analytical errors, sampling and testing materials for use by lay persons must enable safe handling in a home environment. Tests should be designed for feasible use by a lay person, and evaluated by these intended users. Testing information, instructions and post-test interpretation should be designed for consumers with varying degrees of health literacy.
The quality of DTCT must align with their intended use: High-quality DTCT are crucial to reduce errors in the testing process, such as inaccurate results and unnecessary clinical investigations. Minimum test quality standards should align with specific circumstances such as prevalence settings for the condition tested.
The DTCT must provide definitive results for lay interpretation and actions described: Tests should be designed to give clear, conclusive results that laypersons can interpret, and include clear guidance on possible next steps or actions (see point below). Tests that do not define a condition (e.g. provide non-diagnostic information) have poor indications for use, and are ambiguous and difficult for lay interpretation.
DTCT results must not include any recommendations for medical intervention: DTCT are by definition not tests requested within the healthcare system. Without healthcare professionals in the interpretation process, DTCT results should only inform consumers about the need for subsequent medical consultation, not immediate interventions. Non-evidence-based health advice, for example on dietary supplements or repeated testing for non-evidence-based regimens, is not recommended as part of DTCT use.

of regulations across different jurisdictions. A "Consumer Initiated Test (CIT)" label should exist alongside the 'CE-IVD' mark, and tests lacking an evidence-based clinical basis should be clearly labelled.

A clear definition based on consumer initiation would reduce confusion with tests for patients already within medical care, such as near-patient testing, self-collected screening programs, or patient self-monitoring, which are healthcare professional-initiated. Misleading marketing practices contribute to this confusion. For example, although urine glucose test strips can be used for monitoring diabetes patients, they are sold as DTCT for 'diabetes screening,' which is outdated and not evidence-based. Similarly, self-sampling kits for bowel cancer detection, typically used in government or healthcare organization screening programs, are now sold commercially as DTCT to consumers not participating in such programs.

Other recommendations

The DTCT industry and suppliers should take more responsibility in reducing errors, enhancing benefits, and supporting consumers. Establishing advertising and business practice codes can promote ethical practices, reducing consumer harm and overutilization of healthcare resources. Key issues for the industry include improving balanced, scientific information in advertising, ethical use of disclaimers, and preventing data and privacy breaches [1].

Improving consumer decision-support in DTCT should be prioritized. Consumer groups should develop strategies to enhance informed consent before monetary transactions. Consumer-led solutions for incident reporting, product co-design, record management, and participation in real-world trials can ensure greater end-user involvement in the DTCT industry and support consumer empowerment.

Finally, further research on DTCT use and outcomes is needed. Documenting end-user handling of testing by laypersons at home and outcome-based research would monitor the utility of DTCT.

Conclusions

The movement away from traditional clinical testing to consumer initiated testing is purported to empower, not harm consumers; and where testing or sample collection takes place at sites outside of the clinical laboratory and gives consumers more control of the process, this should complement, not add burden to the healthcare system.

The diversity of DTCT modalities and the uneven way in which they are regulated causes confusion for consumers and health professionals alike. This article provides a clear explanation of the various testing pathways and the implications for quality standards and eventual outcomes.

By identifying the key circumvention made to the brain-to-brain total testing process by DTCT, this article highlights the need to look beyond the attributes of test accessibility and personal choice. Ensuring higher quality in the whole testing process must be paramount. As consumers are the main decision-makers when purchasing and conducting these tests, 'consumer initiation' must be the defining characteristic of DTCT in the development of strategies that support them. Establishing dedicated regulation will be a right step in this direction.

Laboratory specialists have a role in advocating that consumers benefit in areas where emerging markets and laboratory medicine intersect. As DTCT has clearly departed from the processes and jurisdictions of the traditional clinical setting, so must the efforts of laboratory specialists expand, and advise on best practice in the use of these tests and to maintain acceptable levels of quality in these new consumer-initiated contexts.

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References

1. Orth M, Vollebregt E, Trenti T, Shih P, Tollanes M, Sandberg S. Direct-to-consumer laboratory testing (DTCT): challenges and implications for specialists in laboratory medicine. Clin Chem Lab Med 2022;61:696–702.
2. Shih P, Ding P, Carter SM, Stanaway F, Horvath AR, Langguth D, et al. Direct-to-consumer tests advertised online in Australia and their implications for medical overuse: systematic online review and a typology of clinical utility. BMJ Open 2023;13:e074205.
3. Ayala-Lopez N, Nichols JH. Benefits and risks of direct-to-consumer testing. Arch Pathol Lab Med 2020;144:1193–8.
4. Precedence Research. Direct-to-consumer laboratory testing market – global industry analysis, size, share, growth, trends, regional outlook, and forecast 2023–2032; 2023. Available from: https://www.precedenceresearch.com/direct-to-consumer-laboratory-testing-market.
5. Exten C, Pinto CN, Gaynor AM, Meyerson B, Griner S, Van Der Pol B. Direct-to-consumer STI testing services: a position statement from the American Sexually Transmitted Diseases Association. Sex Transm Dis 2021;48:e155–9.
6. Plebani M, Laposata M, Lundberg GD. The brain-to-brain loop concept for laboratory testing 40 years after its introduction. Am J Clin Pathol 2011;136:829–33.
7. Lundberg GD. Acting on significant laboratory results. JAMA 1981;245:1762–3.
8. Bloss CS, Schork NJ, Topol EJ. Direct-to-consumer pharmacogenomic testing is associated with increased physician utilisation. J Med Genet 2014;51:83–9.
9. Wilkinson E. The rise of direct-to-consumer testing: is the NHS paying the price? BMJ 2022;379. https://doi.org/10.1136/bmj.o2518.
10. Jones SL, Campbell B, Hart T. Laboratory tests commonly used in complementary and alternative medicine: a review of the evidence. Ann Clin Biochem 2019;56:310–25.
11. Wong A, White H, Plant A, Shipman A, Shipman K. Issues surrounding consumer-bought food-allergy testing. Clin Exp Dermatol 2022;47:547–52.
12. Tidy EJ, Shine B, Oke J, Hayward G. Home self-testing kits: helpful or harmful? Br J Gen Pract 2018;68:360–1.
13. Johnson A, Thompson R, Nickel B, Shih P, Hammarberg K, Copp T. Websites selling direct-to-consumer anti-mullerian hormone tests. JAMA Netw Open 2023;6:e2330192-e.
14. Lovett KM, Mackey TK, Liang BA. Evaluating the evidence: direct-to-consumer screening tests advertised online. J Med Screen 2012;19:141–53.
15. Krogsbøll LT, Jørgensen KJ, Larsen CG, Gøtzsche PC. General health checks in adults for reducing morbidity and mortality from disease. Cochrane Database Syst Rev 2019;2012. https://doi.org/10.1002/14651858.cd009009.pub3.
16. McAlister S, Barratt AL, Bell KJ, McGain F. The carbon footprint of pathology testing. Med J Aust 2020;212:377–82.
17. Scott S, Ozben T, Rampi V, Gruson D, Gammie A, Lopez J, et al. EFLM guidelines for green and sustainable medical laboratories. Milan: European Federation of Clinical Chemistry and Laboratory Medicine; 2022.
18. Galior KD, Baumann NA. Challenges with at-home and mail-in direct-to-consumer testing: preanalytical error, reporting results, and result interpretation. Clin Lab Med 2020;40:25–36.
19. Lundberg GD. The need for an outcomes research agenda for clinical laboratory testing. JAMA 1998;280:565–6.
20. Korenstein D, Chimonas S, Barrow B, Keyhani S, Troy A, Lipitz-Snyderman A. Development of a conceptual map of negative consequences for patients of overuse of medical tests and treatments. JAMA Intern Med 2018;178:1401–7.