European Medical Specialist Review
Official Publication of UEMS | Vol.01, Issue 01, 2026

Point of View: UEMS Should Develop a Position on Direct-to-Consumer Testing (DTCT)

Authors
Birgitte Rode Diness[1], Truls Leegaard[2], Matthias Orth[3]
ORCID: Matthias Orth: 0000-0003-2881-8384 | Birgitte Rode Diness: 0000-0002-9306-3419

Received: 17 March 2026
Accepted: 12 May 2026
Published: 07 August 2026

[1] UEMS Section Medical Genetics; Copenhagen University Hospital Rigshospitalet, Department of Clinical Genetics. Email: Birgitte.rode.diness@regionh.dk
[2] UEMS Section Medical Microbiology; Institute of Clinical Medicine, University of Oslo, Norway and Department of Microbiology and Infection Control, Akershus University Hospital, Norway. Email: tlee@ahus.no
[3] UEMS Section Laboratory Medicine; Vinzenz von Paul Kliniken gGmbH, Institut für Laboratoriumsmedizin, 70199 Stuttgart and Medizinische Fakultät Mannheim, Ruprecht Karls Universität Heidelberg, Mannheim, Germany. Email: matthias.orth@vinzenz.de

Corresponding author: Matthias Orth, matthias.orth@vinzenz.de

DOI: 10.67452/EMSR.2026.013

The UEMS sections representing specialties involved in direct medical laboratory diagnostics collaborate on a wide range of initiatives. This Point of View is a follow-up on discussions in an informal UEMS "Laboratory Diagnostics Interest Group" but not an officially endorsed position paper of the involved sections.

Abstract

The expansion of direct-to-consumer testing (DTCT) presents significant opportunities and risks for patients and healthcare systems. While individual engagement in health is welcome, laboratory testing outside medical structures raises serious concerns about patient safety, result interpretation, and the integrity of healthcare. This Point of View, developed by UEMS sections representing specialties involved in direct medical laboratory diagnostics, argues that UEMS should develop a clear position on DTCT. It examines the ethical responsibilities of medical professionals, the confusion inherent in DTCT marketing, the regulatory gaps that persist across Europe, and the practical consequences of unvalidated testing — including false positives, false negatives, and medicalisation of healthy individuals. The authors call for mandatory labelling, restrictions on medical claims, harmonised EU-level regulation, and active engagement by the medical community to protect patients and preserve the value of medical laboratory expertise.

Keywords: direct-to-consumer testing; DTCT; laboratory medicine; patient safety; regulation; UEMS; medical oversight; self-testing.

Introduction

The expansion of direct-to-consumer testing (DTCT) has created a rapidly evolving market in which individuals can access a wide range of laboratory analyses outside traditional healthcare structures.

This development brings both opportunities and significant challenges. As medical specialists, our primary ethical obligation is to protect patients from harm and to ensure that any test influencing health decisions is safe, meaningful, and interpreted within a clinical context.

Recognising Patient Engagement While Protecting Patients

We welcome individuals who take an interest in their wellbeing. Our intention is not to dismiss patient curiosity or discourage proactive engagement with health. But curiosity must be met with clarity, quality, and responsible guidance. When testing is marketed without appropriate oversight, the risk of harm increases, and the foundational medical principle of doing no harm is compromised. Decisions within healthcare should not be profit-driven. Inside the healthcare system, regulation is in place to protect patients from quacks. For the protection of patients, very tight regulations of marketing exist within healthcare. Outside healthcare, trading is free and the generation of profits a legitimate incentive. But the line between healthcare and "wellbeing products" is blurry, and outside of healthcare, aggressive advertisements including online marketing such as by influencers are legal.

This paper is motivated by that duty: to uphold patient safety, safeguard the integrity of healthcare, and ensure that medical professionals can devote their time to those who genuinely need care.

Many people who purchase DTCT products do so with admirable intentions: they want to understand their bodies better, stay healthy, and make informed choices. This motivation deserves recognition. It reflects a broader cultural shift toward personal responsibility and health awareness.

While the providers will argue that they are marketing well-being products, good intentions should not deprive the citizens/patients of medical safeguards. Laboratory results — whether normal, abnormal, or ambiguous — carry emotional and clinical weight. Without professional interpretation, individuals may misinterpret results, worry unnecessarily, or, more concerningly, be falsely reassured when medical attention is actually needed. As clinicians, we have a responsibility to ensure that patients are not harmed by misleading information or by the absence of appropriate follow-up.

Example 1: False reassurance, negative consequences for individual
A 40-year-old woman is worried due to family history of early onset breast cancer. She requests a genetic DTCT and a lower-than-average risk for breast cancer is reported back based on GWAS studies. For this reason, she does not consult her doctor about the family history.
Five years later she is diagnosed with metastatic ovarian cancer. ***Genetic testing reveals that she is the carrier of a BRCA1 pathogenic variant that was not tested in the DTCT****.*

Example 2: False reassurance, negative public health consequence
A 35-year-old man tests himself for HIV with a test he bought online two weeks after having unprotected sex. He considered the situation high risk for HIV. The test is negative. He is therefore reassured and keeps on having casual sex.

Example 3: Significant decisions for future planning based on unreliable results
Many women worry about their fertility. The "egg timer" blood test (Anti-mullerian hormon, AMH) is marketed to empower women to help them plan when to have children. Online companies are selling the test directly to consumers despite the test cannot predict the likelihood of pregnancy or how long it would take to get pregnant. A 25 year-old women takes the test and receives a normal result, ***this might give her a false sense of security about delaying pregnancy. If she receives a low result, it may cause unwarranted anxiety and depression*** *about not being able to conceive and may cause pressure to conceive earlier than desired or haste towards fertility treatment, such as social egg freezing.*

Example 4: Unnecessary medicalisation

A 35-year-old man is curious about genetics and has genetic DTCTs done. A variant in the gene GLA, associated with Fabry disease, is reported. For this reason, he consults his family physician and request further testing and a heart exam. The GP refers the patient to a cardiologist, who, because of lack of expertise in Fabry disease, refers the patient to a specialist centre where he is finally investigated and cleared from risk of Fabry disease.

Example 5: Paying for a test without any value

Symptoms such as fatigue, heart palpitations, pale skin and breathlessness can be associated with iron deficiency, other patients are even asymptomatic. The qualitative ferritin test performed at home has a cutoff of about 20 ng/ml, i.e. a ferritin below this cutoff should give a negative result. If a person takes this test and receives a positive result, this can indicate iron overload, normal ferritin concentration, or low ferritin - all conditions to be checked by a medical doctor. A negative result can indicate low ferritin or low-normal ferritin, both conditions to be checked by a medical doctor. In all possible constellations, no direct consequences can be drawn from the self test since all test results have to be repeated by a quantitative serum ferritin assay to decide to start iron supplementation or to confirm that there is no need for substitution.

Opportunities and Risks of DTCT

There are contexts in which elements of self-testing can be beneficial. Validated self-collection methods, such as certain human papilloma virus (HPV) sampling strategies, can improve access and participation in screening programmes. Similarly, self-monitoring in chronic diseases like diabetes empowers patients when performed with medically approved equipment and proper training. Yet these examples succeed precisely because they remain embedded within a medical framework — and both HPV self-sampling and diabetes self-testing are part of healthcare and are not, in our view, to be considered DTCT.

The current commercial DTCT market often operates outside such structures: Providers present lifestyle tests using medical language, blur the distinction between recreational and diagnostic testing, or imply clinical relevance where none exists. Some non-medical laboratories obtain commercial accreditation for a limited number of analytical procedures and then suggest that the entire testing process — including pre-analytics and interpretation performed by consumers — meets human healthcare accreditation standards. This is misleading and undermines trust in legitimate medical laboratories.

The consequences are not theoretical: Even when high-quality tests are performed in low-prevalence populations, the vast majority of abnormal results are false positives. In low-quality tests — such as many DTCT home tests — the situation is far worse. False positives can lead to cascades of unnecessary investigations, psychological distress, and wasted resources, both from the consumer themselves as well as from society as a whole. False negatives can delay essential medical care. And the medicalisation of healthy individuals, driven by commercial incentives rather than clinical need, diverts attention and resources away from patients who truly require medical support.

Ethical Responsibilities and the Role of Medical Oversight

The value of a certain medical test cannot be judged independently of the clinical context. For essentially all in vitro tests, a medical assessment is a prerequisite for the selection of the most appropriate test(s). In DTCT, this medical evaluation is not performed but the marketing of DTCTs suggests a benefit to all buyers. Marketing buzz even puts pressure on the consumer to repeat this (unnecessary) testing frequently and to alert friends and family to the possibility of testing.

Medical laboratory testing is not simply the execution of analytical procedures. It is a clinical act that includes appropriate test selection, quality-assured pre-analytical processes, validated analytical methods, expert interpretation, and responsibility for follow-up. Removing any of these components compromises patient safety.

Our ethical obligation is to ensure that tests influencing health decisions are medically sound. This includes protecting patients from misleading claims, ensuring that results are clinically meaningful, and preventing harm caused by inappropriate testing. It also includes supporting our colleagues across all medical specialties by ensuring that their time is spent with patients who genuinely need medical care — not with individuals distressed by misleading “wellness” panels or non-medical genetic reports.

Confusion in Marketing DTCT

Confusion is a central feature of the DTCT business model. Providers often use medical terminology to market non-medical tests, present unvalidated interpretations as “personalised health insights”, blur the intended use of a test, or label recreational products in ways that imply diagnostic value. This confusion is not benign: It exploits patient trust, creates unnecessary anxiety, and undermines the clarity that is essential for safe medical practice. Some DTCT tests marketed are even complete bogus tests such as bioresonance testing (a pseudoscientific method) from hair for allergies or genetic tests for sports aptitude.

Regulatory and Legislative Needs

Clear legislation is urgently needed to protect patients and maintain the integrity of healthcare systems. Consumers must be able to understand whether an in vitro test is a real medical diagnostic tool, a lifestyle product, or something with no validated clinical relevance. Mandatory labelling — similar to food or cosmetic regulation — would help prevent misunderstandings.

Restrictions on medical claims are also essential. Commercial providers should not be permitted to imply diagnostic value without evidence or to use earlier accreditation of analytical components to suggest medical equivalence.

Finally, given the ease of shipping samples across borders, harmonised EU-level regulation is necessary to prevent circumvention of national laws, particularly in areas such as genetic testing. A challenge is that essentially all DTCT are services and not medical products. Services are regulated under national laws while medical products are regulated by the Medical Device Regulation (MDR) and Regulation (EU) 2017/746 (IVDR) (In Vitro Diagnostic Regulation).

Recommendations for the Medical Community

Non-medical test results should not be integrated into healthcare records, to avoid inappropriate clinical decisions based on unvalidated data. Medical professionals should work together to educate patients about the differences between medical and non-medical tests, advocate for appropriate regulation, and support validated self-collection methods when embedded in clinical pathways. We must also highlight the value of medical laboratory expertise in ensuring accurate, clinically meaningful results. Above all, we must continue to prioritise patient safety and uphold the ethical principle of do no harm.

Conclusion

Direct-to-consumer testing is likely to remain part of the health landscape. Patient curiosity and engagement are positive forces, but they must be supported by clarity, quality, and clinical responsibility. As medical specialists, our duty is to protect patients from harm, ensure that testing remains meaningful and safe, and preserve the integrity of healthcare systems. By promoting appropriate regulation, transparent communication, and collaboration across disciplines, we can ensure that clinicians spend their time where it matters most: with the patients who truly need medical care. For these reasons, the UEMS should develop and promote a clear position on the matter.

Key Definitions

Direct-to-Consumer Testing (DTCT) Laboratory analyses marketed directly to individuals without the involvement of a medically qualified professional. DTCT includes the use of home-testing devices and the self-collection of samples sent to medical or commercial laboratories. The latter is also named Direct Access Testing (DAT). DTCT is not part of healthcare.

Self-Collection The process by which individuals collect their own biological samples (e.g., saliva, capillary blood, vaginal swabs) for subsequent laboratory analysis. Self-collection can be appropriate when validated, quality-assured, and embedded in a clinical framework. It should not be equated with "testing": Testing is the analytical process of measuring the concentration of a substance in a body fluid in vitro.

Medical Laboratory Testing / Healthcare Testing Testing performed within medical laboratories under the responsibility of medically qualified laboratory specialists after a medical initial assessment has been made. This includes oversight of pre-analytical, analytical, and post-analytical phases, as well as clinical interpretation and responsibility for follow-up. A special form is self-testing of diabetics where the testing is ordered within healthcare, paid for by the health insurances, and the patient trained by healthcare professionals.

Recreational or Lifestyle Testing Tests marketed for curiosity, entertainment, or general wellness claims. These tests do not meet the standards of medical diagnostics and may not be used to guide any clinical decisions. Lifestyle is used as a loophole to avoid healthcare patient protection regulations (such as by wrong claims, aggressive marketing). In Europe, almost all citizens have universal health coverage. The concept of DTCT is to invent a need for additional testing by using the term lifestyle testing despite essentially all rational in vitro testing being covered by health insurance.

Recommended Additional Literature

1. Gerdes A-M, et al. Direct to consumer genetic testing in Denmark — public knowledge, use, and attitudes. European Journal of Human Genetics. 2021;29(5):851–860.
2. Shih P, 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(12):e074205.

3. Orth M, Sandberg S, Shih P. Direct-to-Consumer Testing: Benefits and Concerns of Commercially Accessed Laboratory Tests. Clin Chem. 2025;71(6):652–663.

4. Jacobs JW, et al. Wellness testing in blood donation: A framework for responsible innovation. Transfusion. 2026.

5. Davenport C, et al. Direct-to-consumer self-tests sold in the UK in 2023: cross sectional review of information on intended use, instructions for use, and post-test decision making. BMJ. 2025;390:e085546.

6. Orth M, et al. Opinion: redefining the role of the physician in laboratory medicine in the context of emerging technologies, personalised medicine and patient autonomy ('4P medicine'). J Clin Pathol. 2019;72(3):191–197.