

Opinion Paper

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Delivering the EU Safe Hearts Plan: the essential role of laboratory medicine in cardiovascular health

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Abstract: The European Union Safe Hearts Plan provides an opportunity to strengthen cardiovascular prevention, early detection, treatment, and monitoring across Europe. This EFLM position paper argues that laboratory medicine must be recognized as a central component of its implementation. Reliable and harmonized laboratory data underpin cardiovascular risk assessment, diagnosis, therapeutic guidance, longitudinal monitoring, and evaluation of population outcomes. Beyond the minimum health-check dataset, tiered and personalized pathways should integrate established biomarkers, specialist testing, and validated emerging technologies. EFLM proposes five priorities: embedding laboratory expertise in governance; translating core testing into personalized pathways; expanding equitable access through quality-assured decentralized models; linking testing to clinical action and value-based financing; and accelerating responsible innovation while strengthening professional capability. By connecting screening with diagnosis, treatment,

and measurable outcomes, laboratory medicine can provide the quality, interpretation, and data infrastructure required to transform the Safe Hearts Plan from policy ambition into equitable cardiovascular health gains across Europe.

Keywords: cardiovascular disease; laboratory medicine; biomarkers; EFLM; prevention; value-based diagnostics

Introduction

Cardiovascular disease remains the European Union's leading cause of death and disability, accounting for approximately 1.7 million deaths each year and affecting an estimated 62 million people [1, 2]. The EU Safe Hearts Plan therefore marks a major policy milestone: it is the first comprehensive European framework dedicated to cardiovascular health. Built around prevention, early detection and screening, and treatment and care, and supported by digital innovation, research and action on inequalities, the Plan aims to reduce premature cardiovascular mortality by 25 % by 2035 [1]. Achieving this target will require more than political ambition. It will require

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operational pathways, measurable implementation indicators and clear professional accountability.

The European Federation of Clinical Chemistry and Laboratory Medicine (EFLM)'s position is that laboratory medicine must be recognized as a central pillar of the Plan's implementation infrastructure. Laboratory medicine should therefore be recognized not simply as a supporting diagnostic service, but as an essential clinical discipline and the measurement backbone of cardiovascular prevention and care. Accurate, accessible and timely laboratory test results are central to risk prediction, early disease detection, diagnosis, therapeutic guidance and longitudinal patient monitoring. Clinical laboratories provide much of the objective information required for these purposes and for evaluating population-level outcomes. European specialists in laboratory medicine add value well beyond the analytical phase through appropriate test selection, pre-analytical quality, standardization of biomarkers' measurements and reported test results, clinical interpretation of test data, data stewardship and the translation of results into actionable care. Without high-quality, comparable laboratory data and longitudinal monitoring, evidence-based cardiovascular medicine cannot be effectively and safely practiced.

The Plan's emphasis on 'knowing one's numbers' illustrates this point. Blood pressure, routinely measured lipid parameters and glycemic markers are central to prevention and early intervention, and the Plan sets ambitious coverage targets for their measurement [1]. The proposed European Cardiovascular Health Check Protocol further recommends a minimum common dataset that includes a standard lipid profile, lipoprotein(a) at least once in life, glucose or HbA1c, and kidney assessment through creatinine-based estimated glomerular filtration rate and albuminuria, combined with validated clinical risk assessment [3, 4]. This is an essential foundation, but it should be regarded as a minimum dataset rather than the full laboratory contribution to cardiovascular health. In selected patients, advanced lipoprotein phenotyping, including quantification of lipoprotein subclasses, may complement conventional lipid measurements and refine assessment of atherogenic burden [5, 6].

The laboratory arsenal available across the cardiovascular care continuum is substantially broader. Depending on the clinical question and level of risk, it may include more detailed assessment of atherogenic lipoproteins through non-HDL cholesterol, apolipoprotein B and, in selected settings, lipoprotein subclass analysis; cardiac-specific biomarkers such as natriuretic peptides and high-sensitivity cardiac troponins; and tests supporting the evaluation of renal, metabolic, inflammatory, haematological and haemostatic status. Lipoprotein subclass analysis and mass spectrometry-based apolipoprotein profiles may provide complementary information on

lipoprotein particles distribution and atherogenic burden, although its incremental clinical utility, standardization and place in care pathways should be established for the intended population. During treatment and follow-up, laboratory testing informs therapeutic selection and intensity, safety monitoring, adherence assessment, and the detection of progression or complications. Genetic and molecular testing can also contribute to the recognition of inherited dyslipidaemias (such as familial hypercholesterolemia), cardiomyopathies and other familial cardiovascular conditions. These capabilities are particularly important for cardiovascular–renal–metabolic health, because atherosclerotic disease, heart failure, diabetes, obesity, metabolic dysfunction-associated steatotic liver disease (MASLD) and kidney disease are interconnected rather than separate clinical silos.

Emerging technologies further expand this potential, and Europe's IVD ecosystem is a strategic asset for translating scientific excellence into accessible, high-quality cardiovascular diagnostics. High-sensitivity analytical platforms, advanced molecular diagnostics, genomics, proteomics, metabolomics, multi-marker signatures and wearable biosensors capable of continuously monitoring selected biomarkers may enable earlier risk detection, more precise disease phenotyping and more personalized monitoring. Established statistical methods remain fundamental, while artificial intelligence can further support the integration and interpretation of longitudinal laboratory results alongside clinical, pathological and radiological findings and other information contained in electronic health records. Such approaches may generate more comprehensive, dynamic and personalized clinical assessments, provided that their performance, explainability, fairness and clinical utility are rigorously evaluated. Connected point-of-care systems and validated remote or self-sampling pathways may also improve access and continuity. These innovations should not be adopted based on technological promise alone: they require robust analytical and clinical validation, standardization, interoperability, ethical governance and evidence of added value [7].

The Safe Hearts Plan should therefore place laboratory medicine at the center of implementation and promote testing strategies that extend from population health checks to targeted risk stratification, specialist diagnosis and longitudinal monitoring. EFLM proposes five priority actions.

Embed laboratory medicine in cardiovascular policy and programme governance

Laboratory specialists should be represented in the design, implementation and evaluation of EU and national

cardiovascular strategies, health checks and screening programmes. Their scientific, clinical and quality expertise is indispensable to govern test selection, analytical performance specifications, reference intervals, clinical decision limits, result interpretation and quality indicators. Common European ambitions must be supported by comparable measurements; otherwise, variation in methods, measurement units and decision thresholds will undermine both equity and evaluation. Laboratory specialists' role in cardiovascular prevention is essential to ensure quality, reliability and patient safety of test-based cardiovascular risk assessment and management strategies. Laboratory medicine provides the measurement, quality, interpretation and data infrastructure needed to make cardiovascular prevention programmes work.

Translate the minimum dataset into tiered and personalized laboratory pathways

The tests explicitly identified in the Plan and the proposed Health Check Protocol should form the first level of a broader laboratory strategy. A population-level core panel should be complemented by targeted second-line testing for individuals with abnormal results, symptoms, family history or elevated clinical risk, and by specialist testing for diagnosis, phenotyping, treatment selection and follow-up. Clear criteria should define when to move from one level to the next, while the choice, frequency and interpretation of testing should be adapted to the individual's evolving risk profile and clinical context. This is the essence of personalized laboratory medicine: using reliable longitudinal laboratory information to deliver the right test, for the right person, at the right time, and to connect each result with an appropriate clinical action. Health checks should therefore initiate coherent care pathways rather than end with isolated measurements.

Expand equitable access through quality-assured delivery models

Citizens should have access to essential cardiometabolic testing irrespective of geography, socioeconomic status or care setting. Delivery may include hospitals, primary care, pharmacies, mobile services and other community-based pathways where these models are clinically appropriate. Point-of-care testing can improve reach and timeliness, but

decentralization must not result in reduced quality performance and clinical governance. Device selection, operator training and competency, internal quality control, external quality assessment, connectivity, traceability, maintenance and clinical governance should remain integrated within laboratory-led quality systems.

Link laboratory testing and data to clinical action and value-based financing

The value of a health check lies not in the number of tests performed, but in whether reliable detection leads to timely prevention, diagnostic confirmation, referral, treatment and improved outcomes. Reimbursement models should therefore support complete pathways rather than isolated analytical acts. They should also discourage inappropriate and excessive testing, which can generate false-positive findings, unnecessary downstream investigations and substantial avoidable costs, in line with laboratory stewardship initiatives such as Choosing Wisely [8]. Standardized laboratory data can also support registries, quality indicators, real-world evidence, risk prediction and evaluation of inequalities when methods, units, coding systems and reference frameworks are aligned. Implementation indicators should extend beyond testing coverage to include positivity rates, referral completion, treatment initiation, target attainment and patient outcomes.

Accelerate responsible innovation and strengthen laboratory capability

Delivering the Plan will require investment in the evaluation and implementation of emerging biomarkers, high-sensitivity assays, molecular and multi-omics technologies, artificial intelligence, personalized reference limits, data interoperability and connected testing models. It will also require sustained investment in European specialists in laboratory medicine, whose combined expertise in cardiovascular biomarkers, point-of-care governance, data science, patient communication, implementation science and health economics is essential to turn innovation into patient benefit. Innovation should be organized through multi-center validation, common performance requirements, shared data standards and structured health-technology

assessment so that promising technologies can move efficiently, but safely, from research into routine care [7].

Equity and patient safety must remain cross-cutting principles. Cardiovascular mortality, diagnostic capacity and access to care vary substantially across and within Member States [1, 2]. Harmonized testing strategies, common quality standards, appropriate reimbursement and carefully governed decentralized services can reduce these gaps. Conversely, poor point-of-care testing results, fragmented digital platforms, inconsistent decision limits and unvalidated direct-to-consumer testing may amplify confusion and inequality. Innovation should therefore be encouraged within a framework of analytical quality, clinical utility, ethics, accessibility and professional accountability.

The Safe Hearts Plan offers Europe a unique opportunity to move cardiovascular care from fragmented intervention towards coordinated, life-course prevention and personalized management. EFLM's position is clear: laboratory medicine and Europe's highly skilled laboratory specialists are indispensable to that transition. Its contribution cannot be reduced to the limited list of tests explicitly named in the Plan: it encompasses a much wider portfolio of established biomarkers, specialist diagnostics, longitudinal monitoring tools and emerging technologies. By providing trusted measurements, actionable interpretation, interoperable data and quality infrastructure, laboratories can connect screening to diagnosis, treatment and outcomes. If the Safe Hearts Plan is to move from policy to measurable outcomes, laboratory medicine needs to be incorporated into governance, quality systems, care pathways, data infrastructure and evaluation. As a proud member of the European Alliance for Cardiovascular Health (EACH), EFLM values the work of its alliance partners and the collective effort to advance cardiovascular health across Europe. EFLM stands ready to work with European institutions, Member States, healthcare professionals, patient organizations and Europe's IVD industry to translate the Safe Hearts Plan from policy ambition into measurable cardiovascular health gains for all Europeans,

while strengthening Europe's capacity for high-quality, equitable and innovative diagnostics.

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References

1. Communication on an EU cardiovascular health plan: the Safe Hearts Plan - public Health n.d. https://health.ec.europa.eu/publications/communication-eu-cardiovascular-health-plan-safe-hearts-plan_en [Accessed 5 Aug 2026].
2. OECD. The State of Cardiovascular Health in the European Union. The State of Cardiovascular Health in the European Union 2025. <https://doi.org/10.1787/EA7A15F4-EN>.
3. A European Cardiovascular Health Plan: The Roadmap cardiovascular-alliance.eu n.d.
4. News Archives - EACH n.d. <https://www.cardiovascular-alliance.eu/category/news/> [Accessed 5 Aug 2026].
5. Zubiran R, Wolska A, Amar M, Sampson M, Remaley AT. Precision medicine for Lipids: the New US Guidelines for dyslipidemia. *Clin Chem* 2026;hvag083. <https://doi.org/10.1093/CLINCHEM/HVAG083>.
6. Langlois MR. Optimising lipoprotein(a) tests: we are almost there. *Clin Chem Lab Med* 2026;64:971–3.
7. Plebani M, Zima T, Gruson D. Strategy of laboratory medicine - EFLM vision. *Clin Chem Lab Med* 2025;64:582–5.
8. Gruson D, Burlacu MC. Appropriate thyroid test ordering: when clinical excellence meets environmental sustainability. *Ann Endocrinol (Paris)* 2026;87. <https://doi.org/10.1016/j.ando.2026.102561>.