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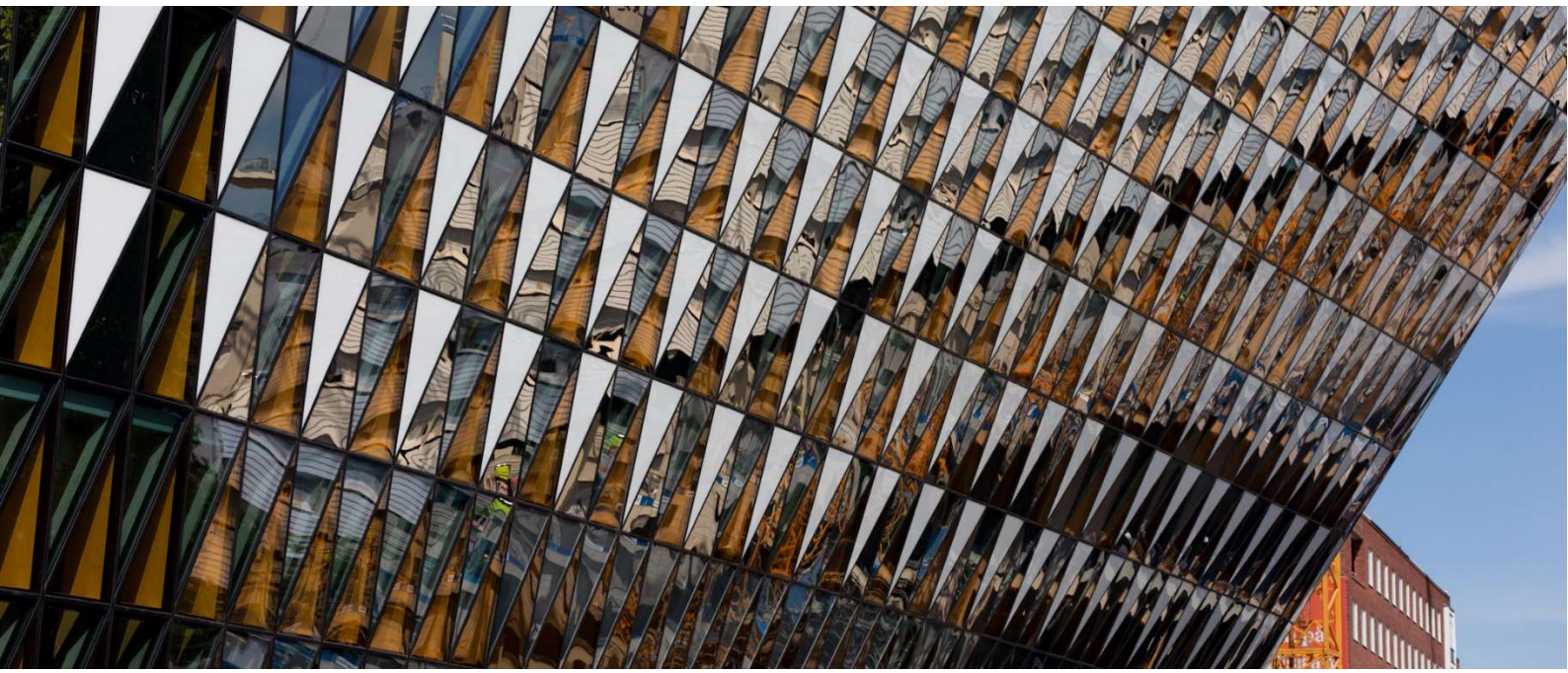
IVD Industry Monograph - No. 3

Beyond Market Access: Foundations for Sustaining Europe's IVD Leadership

Europe has an established and commercially substantial IVD market, and it retains significant industrial leadership: its production footprint appears larger than its share of global demand. This monograph examines the foundations required to sustain that position over time.

Miguel Oliveira



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IVD Industry Monograph Series

The IVD Industry Monograph series is the primary analytical output of Persodia Research. Each monograph examines a single strategic question at the intersection of industry structure, clinical deployment, and market economics, applying the framework developed in Inside the Clinical Diagnostics Industry: Constraints Shaping Strategy — Towards Health Intelligence (Oliveira, 2026) and grounded in the accumulated professional experience of the authors. The monographs are not summaries of that book. They are applications of its framework to specific questions, populated with evidence gathered through structured observation at major IVD industry conferences and through ongoing engagement with industry leaders. The series is observational rather than prescriptive — its purpose is to clarify the structural conditions within which decisions must be made, and in doing so to support the quality of thinking that develops professionals, their organisations, and the industry as a whole. Each monograph stands alone as a complete analytical unit; together they build toward a coherent structural account of the IVD industry as it evolves. Where a monograph identifies structural conditions that require deeper quantitative or sectoral differentiation than a single observational publication can carry, it frames that further analytical work explicitly — positioning it as a natural continuation of the Persodia Research programme rather than a limitation of the present volume. Readers with relevant experience or perspectives are welcome to engage with the authors.

Previous monograph in this series:

Monograph No. 1 — Crossing from Analytical to Diagnostics: The Difficulty is the Moat
Examines the structural distance between the analytical and diagnostics industries — why superior measurement capability does not translate automatically into diagnostic market position, and what the conditions for crossing actually require. Available through the Persodia Research repository at persodia.org.

Monograph No. 2 — Earning Position: How Evidence Becomes Authority
Examines the evidence architecture required to convert market entry into clinical adoption, and the structural conditions that determine whether that evidence achieves durable practical authority.

This volume

Monograph No. 3 — Beyond Market Access: Foundations for Sustaining Europe's IVD Leadership
Examines the structural foundations on which a financially viable, strategically capable and publicly consequential European diagnostics sector depends, and the cumulative industrial conditions now shaping the continuity of those foundations.

Cover photo

Aula Medica, Karolinska Institutet — Diagnostics is part of the infrastructure of care before it is a category of procurement.

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Stockholm, May 2026

MedTech Forum Stockholm 2026 became a turning point in the preparation of this monograph.

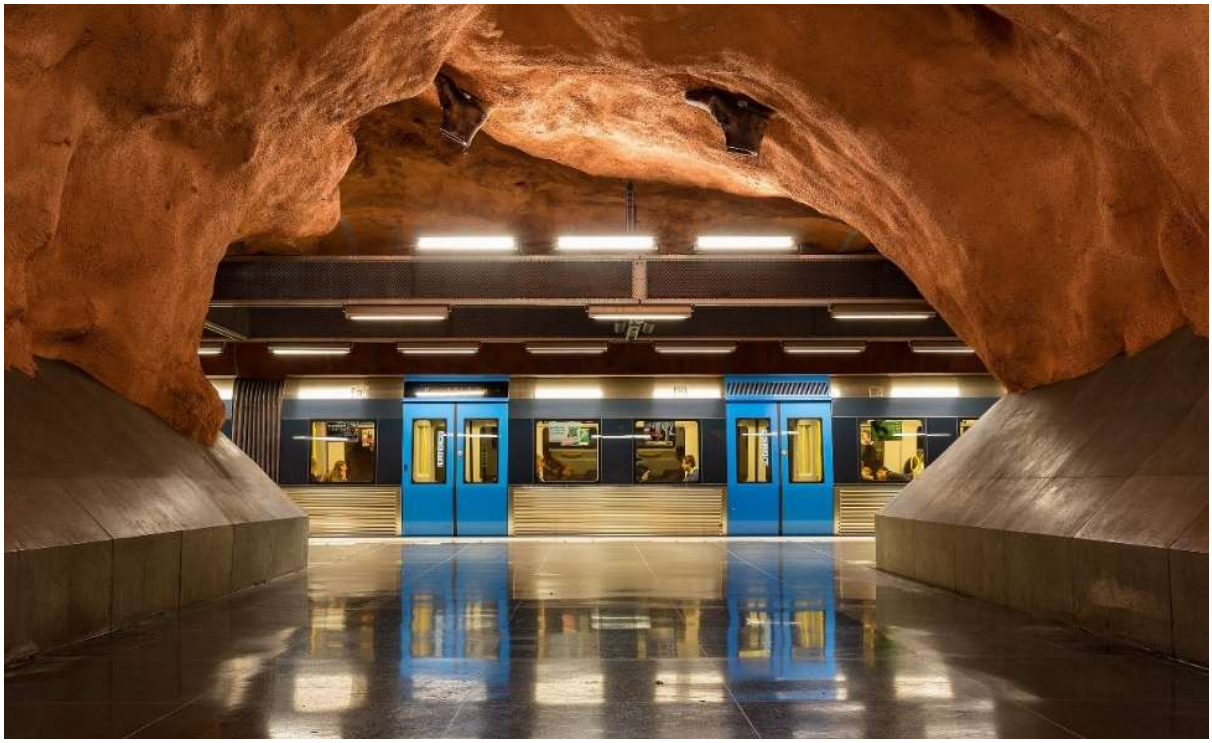
The agenda covered regulation, reimbursement, AI, sustainability, data interoperability and manufacturing. Yet the signal emerging across those sessions was narrower and sharper than any single topic. Two concerns dominated formal sessions, corridor conversations and closed-door exchanges: the competitiveness of European industry and its long-term industrial resilience.

What was not disputed was Europe's scientific depth, clinical expertise, engineering capability and industrial know-how. The foundations remain strong.

What is under pressure is the system around those foundations. The path from innovation to sustainable market participation is too long, too expensive and increasingly difficult to finance — not because ideas are absent, but because friction accumulates at every stage. Regulatory authorisation does not create market access. Registration is only the first gate. HTA, reimbursement, procurement and clinical adoption each operate under their own institutional logic, timeline and criteria — country by country, across a union that coordinates economically but still operates politically.

Stockholm also widened the frame. Diagnostic industrial capacity is not only a healthcare question. It is a strategic resilience question. A region unable to manufacture, renew and sustain the biological measurement infrastructure its healthcare systems depend on carries a structural vulnerability that becomes visible under stress — when it is already too late to rebuild.

The five structural gaps described in Chapter 4 are what that friction and vulnerability look like from inside the industry. Stockholm confirmed the diagnosis. The analysis that follows examines the evidence behind it.



Stockholm Metro — Surface continuity depends on deeper systems remaining functional. Diagnostics follows the same logic.

Executive Summary

Diagnostics is most visible when something fails: a test is unavailable, a result is delayed or a reagent shortage interrupts a laboratory. In ordinary times, diagnostics remains in the background of care. It is assumed to work. That invisibility is part of its success — and part of its vulnerability.

Its industrial role extends beyond its own healthcare systems. Persodia modelling indicates that Europe accounts for approximately **USD 49 billion** of global physical IVD manufacturing output, compared with approximately **USD 33 billion** of regional market demand. Europe supplies the world, not only itself.

The question is whether the foundations supporting that position are strong enough to sustain renewal over time.

Five signs justify closer attention.

The MedTech Europe-reported IVD segment has represented a progressively smaller share of European healthcare expenditure, declining from approximately **0.8%** in 2009 to approximately **0.6%** in 2023. Inflation has absorbed much of nominal market growth. Diagnostic use can expand without proportionately strengthening supplier economics. Capital must cross more institutional gates before returning. Regulatory, digital and evidence obligations fall unevenly across companies of very different scale.

None of these signs indicates immediate failure. Together, they suggest that the conditions required to invest, renew platforms and preserve industrial capability over time are becoming less secure.

The established market-reporting framework provides a valuable reference point, but it does not capture the full economic and industrial perimeter of diagnostics. Important categories, capabilities and suppliers remain less visible within conventional market reporting. This matters because the quality of the debate around Europe's diagnostic future depends partly on how clearly the industry's contribution can be seen.

This monograph examines five structural gaps beyond market access and the corresponding foundations required to sustain Europe's IVD leadership: competitiveness and procurement; fixed-burden absorption; value capture and investment returns; scale-up and market entry; and industrial plurality and resilience.

The central argument is limited but consequential. Product availability does not demonstrate industrial health. A market can remain supplied while investment capacity weakens, specialist capability narrows and dependence on a smaller number of industrial actors increases.

A MARKET CAN REMAIN SUPPLIED WHILE THE INDUSTRY BEHIND IT BECOMES HARDER TO RENEW.

Europe has IVD capacity. Preserving it requires the conditions that allow the industry to invest, renew, scale and remain sufficiently plural over time.

1 Europe's Diagnostics Capacity

Every day, millions of people across Europe depend on diagnostic information across hospitals, laboratories, primary care and the home.

Each result relies on an industrial system operating largely out of sight: infrastructure, manufacturers, service teams, software providers, logistics networks and upstream suppliers.

Europe starts from a position of real strength. This chapter establishes the demand, access infrastructure and industrial capacity that support its IVD leadership.

Section				
1.1 Europe's Population Health Need	1.2 Diagnostic Access Infrastructure Across the Patient Journey	1.3 The European IVD Industry: Definition and Scope	1.4 Europe in the Global IVD Market	1.5 Manufacturing in a Global Economy
Question answered				
What creates Europe’s structural demand for diagnostics?	How does diagnostic capability reach people across laboratories, professional settings and the home?	What industrial layers make dependable diagnostic access possible?	How is European demand structured across countries, access layers and laboratory segments?	What industrial capacity serves that demand, and how strongly is it anchored in Europe?

> Europe has substantial diagnostic capacity. Sustaining it requires the industrial foundations behind it to remain strong.

1.1 Europe's Population Health Need

Diagnostic demand extends across the entire life course.

Newborn screening, antenatal care, acute illness, cancer prevention, chronic-disease monitoring and public-health surveillance all depend on reliable diagnostic access. Diagnostics is not confined to episodes of disease. It supports prevention, treatment selection, follow-up and population readiness.

Europe serves approximately **450 million** people. Its population is ageing: around **99 million**, or **22%**, are already aged 65 or above. By 2050, the share is projected to approach **30%**.[24]

Ageing matters because it increases the prevalence of chronic disease, multimorbidity, cancer and cardiovascular conditions. These require repeated diagnostic contact over time rather than isolated testing events.

The demand base is broader still. Children require screening programmes. Younger adults need diagnostics for acute illness, reproductive health and genetic risk. Healthy populations participate in prevention and surveillance. During public-health crises, diagnostic demand can expand rapidly across the population.

Dimension	EU-27 figure
Population served	450.6 million, 1 Jan 2025
Population aged 65+	22.0% / ~99.1 million, 1 Jan 2025
Projected aged 65+ by 2050	~29.4%
Current health expenditure	€1.72 trillion / 10.0% GDP, 2023
Per-capita health expenditure growth	4.1% CAGR, 2014–2023, nominal/current-price

Source: Eurostat. Population series; Eurostat. Healthcare expenditure statistics (SHA series). Extracted 2025–2026. OECD and European Commission. Health at a Glance: Europe 2024. CAGR – Compound Annual Growth Rate

Europe's healthcare systems must support four forms of demand simultaneously: diagnosis, monitoring, prevention and public-health readiness.

This demand is largely shaped by publicly funded or regulated healthcare systems. Broad access is therefore accompanied by sustained cost pressure, procurement discipline and increasing expectations for efficiency.

> Europe's diagnostic demand is structural: broad, recurring and embedded across the full patient journey.

1.2 Diagnostic Access Infrastructure Across the Patient Journey

Diagnostics follows the patient across the healthcare journey.

Screening, primary care, hospital treatment, specialist pathways and long-term monitoring each require different combinations of access, speed and clinical oversight. The infrastructure serving these needs extends from central laboratories to professional point-of-care settings and consumer self-testing.

The clinical-laboratory layer remains the core of the system. Persodia Research estimates approximately **24,310** clinical laboratory and testing facilities across the EU27, EFTA and the United Kingdom, supporting around **849 million patient episodes** per year — approximately **2.33 million** on an average day. These are patient episodes, not individual assays: each episode may involve multiple tests across several analytical platforms.[4]

Professional point-of-care testing extends access into primary care, pharmacies, urgent care and long-term-care settings. Europe has an estimated **557,213** potential professional POC sites, of which approximately **195,024** meet practical near-term adoption conditions.

Consumer self-testing adds a third layer. Across chronic monitoring, respiratory, reproductive and wellness testing, the estimated potential reach is approximately **89.7 million** annual beneficiaries.

Access layer	Facilities / people reached	Daily relevance
Clinical laboratories	24,310 clinical laboratory / testing facilities	~2.33 million lab patient episodes per day
Professional POC	557,213 potential professional POC sites	195,024 near-term addressable sites
Consumer self-testing	89.7 million potential annual beneficiaries	~245,700 average daily-equivalent beneficiaries

Source: Persodia Research. European Lab Landscape. Internal analytical study, 2026.

The three layers are complementary. Central laboratories provide scale and analytical depth. Professional POC brings selected decisions closer to the patient. Consumer testing extends access beyond conventional care settings.

> Europe's diagnostic capacity depends on an access infrastructure operating across laboratories, professional settings and the home.

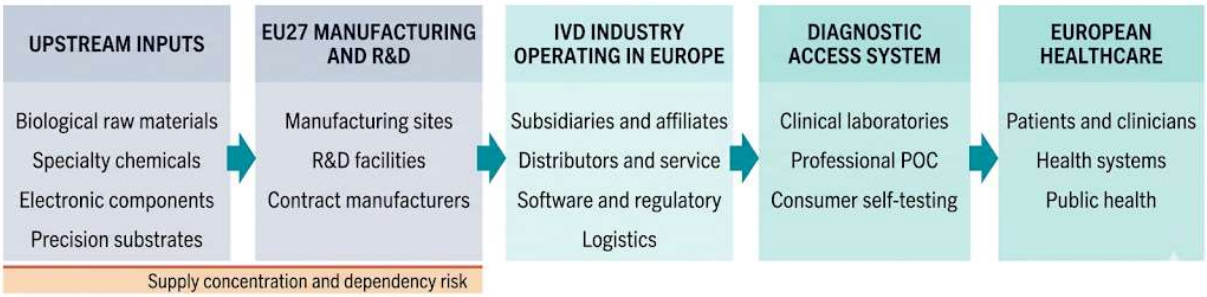
1.3 The European IVD Industry: Definition and Scope

The in-vitro diagnostics industry is the industrial system that makes diagnostic information reliable, timely and available at scale.

Most people never see it. They notice it mainly when a test is unavailable, a result is delayed or a laboratory cannot operate normally.

Its economic profile is unusual. IVD expenditure represents less than **1%** of healthcare spending across the EU27, EFTA and the United Kingdom, while diagnostic results support decisions across the patient pathway — from screening and admission to therapy selection, discharge and long-term monitoring.[26]

The industry extends well beyond the companies that sell tests. It begins with upstream inputs and continues through manufacturing, R&D, service, software, logistics and access infrastructure before reaching patients, clinicians and health systems.



Two distinctions matter.

First, the IVD industry operating in Europe is not the same as European manufacturing capability. Europe can remain well supplied and serviced even while part of its production and R&D base shifts elsewhere.

Second, upstream dependencies can develop long before shortages become visible. Biological raw materials, specialty chemicals, electronic components and precision substrates sit at the least visible part of the chain, but they influence cost, security of supply and the ability to renew capacity.

European diagnostic strength therefore depends on more than market access. It depends on the industrial layers that make access durable.

> The IVD industry is the largely invisible system that turns scientific capability into dependable diagnostic access.

1.4 Europe in the Global IVD Market

Europe has an established and commercially substantial IVD market. Demand is large, diversified and concentrated in a limited number of national healthcare systems.

Demand is concentrated in a small number of countries

The EU27+ reporting perimeter comprises 31 countries: the EU27, the United Kingdom, Switzerland, Norway and Iceland.

A small group of national markets accounts for most regional demand.

Market group	Countries	Number	Share
Large markets	Germany, France, Italy, Spain, United Kingdom	5	65.6%
Medium-sized markets	Netherlands, Switzerland, Poland, Belgium, Austria	5	17.3%
Smaller markets	Remaining European countries	21	17.1%
Total		31	100.0%

Source: MedTech Europe. European IVD Market Statistics Report 2025. Brussels, 2025. Persodia Research. European Market Study. Internal analytical study, 2026.

This concentration matters. European regulatory access does not remove national differences in reimbursement, procurement, laboratory organisation and commercial scale.

The five largest national markets account for almost two-thirds of regional demand. Their procurement rules, reimbursement systems and laboratory structures therefore shape a substantial part of the commercial environment. Medium-sized markets remain relevant, but the economics of participation differ materially from those of the largest systems. Smaller markets often require different approaches to distribution, service and portfolio prioritisation.

Europe is a large regional market, but it does not operate as a single commercial system.

Laboratory demand remains dominant

European demand spans three principal access layers: clinical laboratories, professional point-of-care testing and consumer diagnostics.

The laboratory remains the economic and clinical centre of the market. Consumer diagnostics and professional POC extend access beyond conventional settings, but decentralisation has not displaced the central role of laboratory testing in either market value or clinical impact.

European market layer	Sales, USD bn	Share of European market
Laboratory	26.9	81.3%
Consumer	4.0	12.2%
Professional POC	2.2	6.6%
Total	33.1	100.0%

The growth of consumer and professional POC testing is strategically important. It broadens access, changes workflow expectations and moves selected decisions closer to the patient.

The pattern is one of layering, not substitution. Central and specialised laboratories continue to provide the analytical depth, menu breadth, quality systems and operational scale required for most diagnostic activity. Decentralised testing expands the perimeter of the market. In professional and hospital POC settings, it often remains connected to laboratory-led quality assurance, clinical governance and referral pathways.

Laboratory demand combines routine testing, specialised diagnostics and workflow infrastructure

The laboratory market is not a single category. It includes high-volume routine testing, specialised clinical diagnostics and the systems required to move samples, data and results through the pathway.

Laboratory demand layer	Main categories	Sales, USD bn
Routine laboratories	Clinical chemistry, haematology, microbiology	16.0
Specialised laboratories	Immunology, clinical genomics, pathology, etc.	6.8
IT and workflow	Sampling, pre-analytics, workflow systems	4.1
Laboratory total		26.9

Source: Persodia Research. Global Market Study. Internal analytical study, 2026.

Routine testing provides the volume base. Specialised diagnostics support more differentiated clinical decisions. Sampling, data and workflow infrastructure enable the system to operate at scale.

These layers are economically and operationally interdependent. Routine testing sustains throughput and installed-base density. Specialised diagnostics increase clinical depth and reinforce the relevance of laboratory expertise. IT, pre-analytics and workflow systems connect both, allowing results to move reliably through increasingly complex care pathways.

What this establishes

Europe is one of the principal demand regions of the global IVD industry: commercially substantial, concentrated in a limited number of national healthcare systems and still anchored in the laboratory despite continued decentralisation. Europe is a large diagnostics market, but its demand remains concentrated and fundamentally laboratory-centred.

1.5 Manufacturing in a Global Economy

Europe is not only a major diagnostics market. It is also an industrial platform serving global demand.

The Persodia Global Market Study estimates that the European Union accounts for approximately **USD 49.0 billion** of physical IVD manufacturing output, compared with approximately **USD 33.1 billion** of modeled European regional sales.[6]

Industrial indicator	USD bn
Europe Market	33.1
EU manufacturing Value	49.0
EU share of global manufacturing	37.9%
EU output / Europe market	1.48x
Modeled output-demand diff.	15.9

Physical manufacturing output is not the same as trade balance, value added or capital ownership. The comparison is a directional indicator of Europe's industrial role.

The result is clear: Europe manufactures more diagnostic products than its own healthcare systems consume. Its industrial role extends beyond regional continuity into the global supply architecture of the IVD industry.

Manufacturing strength is substantial but uneven

European industrial capability is not distributed evenly across diagnostic segments.

The strongest modeled positions are visible in established laboratory systems and infrastructure-related categories. Several newer or more decentralized segments show thinner European manufacturing depth.

Europe retains strong manufacturing depth in clinical chemistry, workflow infrastructure, immunology and consumer diagnostics. Professional POC and clinical genomics are less strongly anchored. Clinical genomics is the clearest modeled capability-gap signal and warrants deeper analysis.

The following figures are directional indicators, not product-level dependency measures.

Diagnostic segment	EU output	EU share
IT&Workflow	6.5	46.8%
Clinical chemistry	13.3	46.5%
Immunology	3.2	43.5%
Hematology	3.8	34.2%
Transfusion	1.4	33.4%
Microbiology	6.9	31.0%
Transplant	1.2	31.3%
Pathology	1.1	27.9%
Clinical genomics	1.2	17.3%
Professional POC	2.5	25.8%
Consumer	8.1	44.4%
Total	49.0	37.9%

Source: Persodia Research. Global Market Study. Internal analytical study, 2026. Persodia Research. IVD Segment & Product Taxonomy. Reference Document, Version 1.0. May 26

The manufacturer base is broad but geographically concentrated

The Persodia IVD Manufacturers Census identifies approximately **1,042** known Europe-based manufacturer records across the European reporting perimeter.[7]

Group	Countries	Number
Largest base	Germany	239
Major ecosystems	UK, IT, FR	359
Other ecosystems	ES, CH, NL, SE, PL, DK	254
Other EU countries		190
Total		1,042

Source: Persodia Research. IVD Manufacturers Census. Internal analytical study, 2026.

The census maps the breadth and geography of the industrial base. It does not measure production output.

Germany accounts for almost one-quarter of the known Europe-based manufacturer records. The United Kingdom, Italy and France also retain substantial ecosystems. Beyond these countries, the base becomes progressively more fragmented.

This concentration matters. Industrial continuity depends not only on corporate headquarters, but also on manufacturing expertise, R&D capacity, technical-service networks and specialist suppliers embedded within regional ecosystems.

European industrial capability is not defined by headquarters nationality alone. Non-European groups maintain manufacturing, R&D, service and commercial infrastructure within Europe, while European-headquartered groups also operate important capabilities outside the region. The relevant question is where industrial capacity is located, sustained and renewed — not only where corporate ownership resides.

External trade confirms Europe's industrial relevance

Reported trade data provides an independent, narrower confirmation of Europe's export role.

In 2024, the EU27 exported approximately **USD 13.0 billion** of diagnostic reagents and medical test kits and imported approximately **USD 6.6 billion**, generating a positive external trade balance of approximately **USD 6.4 billion**.[1032]

EU27 external trade, 2024		USD bn
Imports		6.6
Exports		13.0
Net trade balance		+6.4

Largest origins	Share	USD bn
United States	58.2%	3.9
United Kingdom	12.7%	0.8
China	6.2%	0.4
Largest destinations	**Share**	**USD bn**
United States	24.6%	3.2
China	12.7%	1.7
Saudi Arabia	3.9%	0.5

Source: World Bank WITS / UN Comtrade. EU imports and exports of HS 382200, 2024. Persodia Research calculations.

The trade figures cover a defined goods category. They are not equivalent to the total IVD market and do not capture instruments, software, services or all upstream dependencies.

They nevertheless reinforce the same conclusion: Europe remains a meaningful export-oriented diagnostics platform.

Industrial capacity is broader than manufacturing alone

Manufacturing output is only one part of diagnostic capability.

Continuity also depends on upstream inputs, regulatory and quality functions, lifecycle evidence generation, technical-service networks, logistics, software, middleware, cybersecurity and specialist suppliers serving lower-volume categories.

European IVD capability is therefore real but uneven. It combines substantial physical manufacturing, strong positions in several core segments, a broad but geographically concentrated manufacturer base and a positive external trade position.

What this establishes

Europe retains substantial IVD industrial capability. It is not only a destination market; it is part of the global supply architecture of diagnostics.

Its position cannot be assumed to renew automatically. Industrial depth varies materially by segment, remains concentrated in a limited number of national ecosystems and depends on capabilities that extend well beyond finished-product manufacturing.

> Europe supplies the world, not only itself. Sustaining that position requires continued industrial renewal.

2 Five Societal Expectations for Diagnostics

Diagnostics is expected to do more than produce reliable test results.

Across clinical practice, public-health preparedness, payer priorities, regulation and patient pathways, its role has broadened. Earlier decisions, more efficient care, precision medicine, resilience and digital integration increasingly depend on diagnostic capability.

The five expectations below describe the functions healthcare systems now place on diagnostics.

EARLIER AND MORE ACCURATE CLINICAL DECISIONS	MORE EFFICIENT HEALTHCARE DELIVERY	PRECISION MEDICINE AND INNOVATIVE CARE	SYSTEM RESILIENCE AND PUBLIC-HEALTH READINESS	DIGITAL, REGULATORY AND EVIDENCE INFRASTRUCTURE
Expectation				
Reduce uncertainty earlier in the patient pathway	Use constrained healthcare resources more effectively	Enable therapy selection and more differentiated care	Support preparedness, surveillance and emergency response	Operate within connected, secure and continuously regulated healthcare systems
Where it is visible				
Screening, triage, diagnosis, therapy selection and monitoring	Faster decisions, laboratory automation, workflow integration and appropriate testing	Companion diagnostics, molecular profiling, resistance testing and biomarker monitoring	Pandemic response, antimicrobial resistance, emerging pathogens and supply continuity	IVDR lifecycle obligations, health-data integration, cybersecurity and AI-enabled diagnostics

> The role of diagnostics is expanding. The capacity required to sustain it must keep pace.

2.1 Earlier and More Accurate Clinical Decisions

Healthcare systems increasingly expect diagnostics to reduce uncertainty earlier in the patient pathway.

Screening, triage, diagnosis, therapy selection and monitoring all depend on information being available at the right moment. Earlier diagnosis can shorten the path to intervention, improve resource allocation and reduce avoidable disease escalation. This expectation is explicit in European policy areas such as cancer screening and early detection.[15]

Speed alone is not enough. Diagnostic information must also be analytically reliable, clinically meaningful and usable within real care workflows. A technically correct result creates limited value if it arrives too late, remains disconnected from clinical systems or cannot guide action.

Requirement	**Industrial implication**
Analytical reliability	Continuous platform investment, quality maintenance and lifecycle control
Clinical validity	Evidence generation across relevant populations and clinical settings
Turnaround time	Service depth, installed-base support and workflow integration
Guideline alignment	Medical-affairs capacity and sustained clinical partnership
Digital integration	Interoperability with laboratory systems, electronic health records and clinical workflows
Operational continuity	Training, technical support, spare-parts availability and resilient supply chains

For the IVD industry, this creates a continuous obligation. Suppliers must maintain assay performance, generate evidence, sustain platforms and support implementation as clinical needs evolve. Under the IVDR, part of this expectation is formalized through requirements covering scientific validity, analytical performance and clinical performance.[19]

Procurement decisions focused only on unit price do not capture these capabilities. Their value is visible when results arrive reliably, integrate into care and support decisions without delay.

> Earlier decisions depend on capabilities maintained long before the result reaches the clinician.

2.2 More Efficient Healthcare Delivery

Healthcare systems are expected to deliver more care with constrained resources.

Ageing populations and chronic disease increase demand, while shortages of trained personnel limit capacity. Diagnostics is therefore expected to help healthcare systems use time, workforce and budgets more effectively.[29][31]

This expectation is broader than lowering the price of individual tests. Diagnostics creates efficiency when it supports earlier decisions, better triage, more appropriate therapy, fewer repeated investigations and shorter pathways through care. Timeliness matters: a delayed result can postpone treatment, discharge or referral and generate avoidable clinical activity.

The same principle applies inside the laboratory. Automation, middleware and connectivity can reduce repetitive work, improve consistency and help laboratories manage rising volumes with constrained staffing. Professional point-of-care testing can bring selected decisions closer to the patient when speed materially changes the pathway.

Healthcare-system pressure	Societal expectation for diagnostics	Industrial requirement
Rising clinical demand	Faster decisions, better triage and patient routing	Platform renewal and targeted POC investment
Personnel shortages	Reduced manual work and more productive use of clinical time	Automation, middleware and decision support
Budget constraints	Fewer avoidable interventions and earlier discharge	Evidence of clinical and economic value
Fragmented pathways	Timely access to results across care settings	Connectivity and workflow integration
Risk of inappropriate use	The right test at the right point in the pathway	Guideline alignment and training

Efficiency does not justify indiscriminate testing. The expectation is for appropriate diagnostics: the right test, for the right patient, at the right moment, with a result that supports action.[14][33]

For suppliers, this requires continued investment in platforms, automation, software integration, service infrastructure and training. Procurement focused only on unit price risks overlooking the value of uptime, turnaround time and workflow continuity.

> The expectation is not only for cheaper tests. It is for diagnostic capability that makes constrained resources go further.

2.3 Precision Medicine and Innovative Care

Healthcare systems increasingly expect treatment to be matched more closely to the individual patient.

As therapies become more targeted, diagnostics is needed to identify who is likely to benefit, who may face avoidable risk and whether treatment is working. The role of IVD is therefore not only to detect disease, but to enable more precise and effective care.[2520]

Companion diagnostics are the clearest example. They connect medicines to the patients most likely to respond. Molecular profiling can guide cancer therapy according to tumour biology. Resistance testing can improve antimicrobial selection. Biomarker monitoring can indicate whether treatment is effective before deterioration becomes clinically visible.

Therapeutic area	**Societal expectation for diagnostics**
Oncology	Identify eligible patients and guide targeted therapy
Infectious disease	Select appropriate treatment and limit avoidable antimicrobial use
Chronic disease	Monitor response and adapt treatment over time
Advanced therapies	Support patient selection and long-term follow-up

Diagnostics has become part of the infrastructure of therapeutic innovation. Advanced treatments depend on deployable platforms, interpretable results and evidence that clinicians, regulators and payers can trust.

For suppliers, this requires specialized assays, biomarker validation, regulatory depth, bioinformatics capability and partnerships with pharmaceutical companies and clinical institutions. Under the IVDR, companion diagnostics operate within a more demanding evidence and regulatory environment.[19]

> Innovative therapies increasingly depend on diagnostic capability to reach the right patients.

2.4 System Resilience and Public-Health Readiness

Diagnostic systems are expected to remain dependable when healthcare systems come under pressure.

The COVID-19 pandemic made this visible at scale. Pathogen identification, testing expansion, surveillance and public-health decisions all depended on diagnostic capabilities that were already validated, deployed and capable of rapid scale-up.[16]

Resilience cannot be created at the moment of crisis. It depends on standing capabilities: manufacturing depth, secure reagent supply, validated platforms, trained laboratory teams, reliable data flows and effective public-private coordination.

The same expectation applies beyond pandemics. Antimicrobial resistance requires pathogen identification and resistance testing to support more appropriate treatment. Emerging pathogens require rapid assay development and deployment. Supply disruption requires sufficient redundancy and supplier diversity to preserve continuity.[1133]

Threat	Societal expectation for diagnostics	Industrial capability needed
Pandemic	Rapid identification, testing scale-up and surveillance	Manufacturing depth, validated platforms and public-private coordination
Antimicrobial resistance	Pathogen identification and resistance testing at scale	Installed laboratory capability, diagnostic stewardship and rapid access to results
Emerging pathogens	Fast development and deployment of new assays	Scientific expertise, regulatory readiness and flexible production capacity
Supply disruption	Continuity of access to essential tests and reagents	Backup sourcing, supplier diversity and resilient supply chains

For suppliers, resilience requires capacity that may not be fully utilized in normal periods: manufacturing capability, scientific expertise, quality systems, regulatory readiness and supply-chain redundancy.

A weakened industrial base has less ability to absorb shocks, expand production or support laboratories under pressure.

> Resilience is a standing capability, not an emergency project.

2.5 Digital, Regulatory and Evidence Infrastructure

Diagnostics is increasingly expected to operate within a connected, secure and continuously regulated healthcare environment.

A test result is no longer only an analytical output. It must move reliably through laboratory systems, electronic health records and clinical workflows while remaining traceable across the patient pathway.

Digital integration is now part of the product environment. Instruments connect to middleware, hospital networks, cloud platforms and remote-service systems. The European Health Data Space reinforces the direction toward more interoperable health data across care settings.[23]

Regulatory obligations are also continuous. Under the IVDR, manufacturers must maintain technical documentation, performance evidence and post-market surveillance throughout the product lifecycle. Connected systems must also be maintained against cybersecurity risks. NIS2 and the Cyber Resilience Act reinforce the wider expectation that digital products and services remain secure by design, where applicable.[19][18][22]

Expectation	Industrial capability needed
Continuous conformity	Permanent regulatory, quality and vigilance functions
Secure connected systems	Cybersecurity monitoring, software maintenance and incident response
Health-data integration	Connectivity, interoperability and data governance
AI-enabled diagnostics	Technical documentation, validation, traceability and post-market monitoring
Lifecycle evidence	Clinical, analytical and real-world evidence capability

Artificial intelligence adds a further layer. Where applicable, suppliers must address documentation, transparency, oversight and monitoring requirements.[21]

For the IVD industry, digital, regulatory and evidence capabilities are no longer external support functions. They are embedded in the product lifecycle and require sustained investment.

> Digital, regulatory and evidence infrastructure has become part of the product. Its cost is permanent.

3 Five Signs of Insufficient Reinforcement

The analysis in this chapter uses the MedTech Europe reported-market series because it is the only consistent published European-perimeter IVD series available across the reference period. It captures the established association-reporting segment of the industry rather than the full diagnostics economy. Broader Persodia modelling indicates that the wider economic perimeter is materially larger, including categories and suppliers that are incompletely represented in the reported series. This limitation does not invalidate the evidence. It defines its scope. It is also analytically relevant: an industry that is only partially visible in its established reporting framework is harder to assess, compare and reinforce coherently.[9]

Signs				
MTE-reported IVD revenue takes a smaller share of healthcare spending	Inflation absorbs much of the reported market expansion	Diagnostic use rises faster than supplier revenue capture	Capital must cross more institutional gates before returning	Fixed participation costs weigh unevenly across the supplier base
What it indicates				
Supplier participation lags healthcare-system expansion over time	Real reinvestment capacity remains limited across the sector	Higher utilization does not proportionately strengthen supplier economics	Investment cycles become longer, riskier and harder to sustain	Smaller and specialist suppliers face disproportionate pressure

> Present supply continuity can conceal weaker conditions for future renewal.

3.1 Declining Participation in Healthcare Expenditure

The established European IVD reporting segment has represented a progressively smaller share of healthcare expenditure over time.

The ratio declined across every observed anchor period. Between 2009 and 2023, the cumulative reduction reached approximately 24% in relative terms. The full source treatment is shown in Annex 2, Table A2.3a.

The reporting perimeter matters. The MedTech Europe series captures the established association-reporting segment of the European IVD industry, not the full diagnostics economy. Broader Persodia modelling indicates that the wider market is materially larger.

Anchor year	IVD market, €m	CHE, €m	IVD / HCE
2009	10,685	1,344,789	0.80%
2014	10,635	1,413,220	0.75%
2019	11,265	1,683,278	0.67%
2023	13,315	2,204,234	0.60%

Over 2014–2023, the MTE-reported European IVD market grew at a nominal CAGR of 2.5%, compared with 4.4% for current healthcare expenditure. The reported gap is approximately 1.9 percentage points per year.

A central sensitivity scenario allowing for consolidation-related effects narrows the gap to approximately 0.7 percentage points, but does not remove it. The scenario is described in Annex 2.[9]

The participation decline is therefore a documented finding for the established reporting segment. It should not be read as a complete measure of diagnostics as a whole.

> The established IVD reporting segment has grown, but its participation in healthcare expenditure has declined.

3.2 Weak Real Reinforcement

Nominal market growth does not necessarily translate into stronger capacity to reinvest. Revenue may increase in current prices while the cost of sustaining the business rises at the same pace or faster. Salaries, materials, logistics, regulatory compliance, software maintenance, cybersecurity, service infrastructure and evidence generation all absorb part of the apparent expansion before additional resources become available for renewal.

Over 2014–2023, the MTE-reported European IVD market grew at a nominal CAGR of 2.5%. Over the same period, the EU27+ inflation proxy reached 2.7%. Reported real growth was therefore approximately −0.13% per year.

This does not mean that every company experienced the same financial outcome, nor does it measure profitability directly. It indicates that, at the level of the established reporting segment, nominal market expansion did not create a materially larger real-growth envelope from which to finance new platforms, assay development and the expanding obligations of market participation.

Measure	Nominal CAGR, 2014–2023	Inflation proxy	Real CAGR
MTE-reported IVD market	2.53%	2.66%	−0.13%
Central consolidation-adjusted	3.68%	2.66%	+0.99%

Even on this adjusted basis, the real-growth envelope remains modest for an industry expected to renew installed systems, support innovation and absorb rising regulatory, digital, evidence and service obligations.

The figures do not measure profitability, margins or the investment position of individual companies. They indicate that the established reporting segment has experienced little real reinforcement over the period.

> Nominal growth has largely been absorbed by inflation.

3.3 Diagnostic Use Has Grown Faster Than Supplier Revenue

More diagnostic activity does not automatically translate into stronger supplier economics. Testing volumes can rise while the revenue captured per episode remains constrained by reimbursement pressure, procurement intensity and continuous efficiency expectations.

Across healthcare systems, demand expands through ageing, chronic disease, screening, monitoring and broader access. Yet higher utilization does not necessarily create a stronger reinvestment base for the suppliers expected to renew assays, platforms and service infrastructure.

Demand-side signal	What it can indicate
More testing episodes	Greater diagnostic intensity across care pathways
Wider screening and monitoring	Growing use beyond acute clinical episodes
Expansion of decentralized testing	More activity outside conventional laboratory settings
Stable or compressed supplier revenue capture	Rising use does not necessarily reinforce the industrial base proportionately

Available indicators are consistent with a decoupling between diagnostic activity and supplier revenue capture. The evidence should be read directionally: demand-side proxies do not provide a complete Europe-wide measure of test volumes, nor do they map directly onto manufacturer revenue.

The structural point is narrower. Diagnostic use has expanded while the capacity to reinvest, renew platforms and sustain specialist capability remained constrained.

> Rising utilization and constrained supplier revenue are not contradictions. They are the expected outcome of how diagnostic procurement is structured.

3.4 Capital-Duration Stress

IVD investment must cross more gates before it generates durable returns.

A diagnostic product does not move directly from technical development to routine use. It must pass through evidence generation, regulatory approval, reimbursement, procurement, implementation and lifecycle maintenance. Each step adds time, cost and uncertainty.

Capital-duration stage	What it requires
Development and validation	Technical performance, clinical evidence and quality systems
Regulatory access	Conformity assessment, documentation and post-market obligations
Reimbursement and funding	Recognition within national or local financing structures
Procurement and adoption	Tender access, commercial negotiation and clinical acceptance

The industrial challenge is cumulative. Capital remains committed across multiple institutional gates before revenue becomes predictable and before the investment cycle can begin again.

This affects firms differently. Large platform companies can spread delay and compliance costs across installed bases, portfolios and geographies. Smaller and specialist suppliers often carry similar sequencing risks with fewer sources of recurring revenue.

The issue is not simply the cost of innovation. It is the length and uncertainty of the crossing from innovation to sustainable market participation.

> The length of the crossing, not the cost of any single gate, is what makes renewal progressively harder to finance.

3.5 Participation-Burden Asymmetry

Regulatory, digital, evidence, quality and service requirements are necessary to protect patients and sustain trust. Many of these obligations, however, create fixed participation costs that must be absorbed before scale is achieved.

A company must maintain core capabilities even when its portfolio is narrow or its revenue base remains limited. As these obligations accumulate, their relative weight becomes greater for smaller and specialized suppliers.[192728]

Participation burden	Why the effect is uneven
Regulatory documentation and conformity assessment	Minimum compliance costs apply even to narrow portfolios
Post-market surveillance and lifecycle evidence	Ongoing obligations continue after market entry
Quality systems and audit readiness	Required infrastructure does not scale down proportionately
Cybersecurity and digital integration	Technical maintenance expands beyond the original product

The structural concern is not that these obligations exist. It is that their relative weight is higher for smaller and specialized suppliers.[2830]

A broad supplier base supports clinical niches, competition, innovation and resilience. When fixed participation burdens accumulate faster than the capacity to absorb them, smaller companies face stronger pressure to withdraw, consolidate or narrow their portfolios.

The result may remain invisible for some time. Products stay available and major manufacturers remain present, while the industrial base gradually becomes less plural.

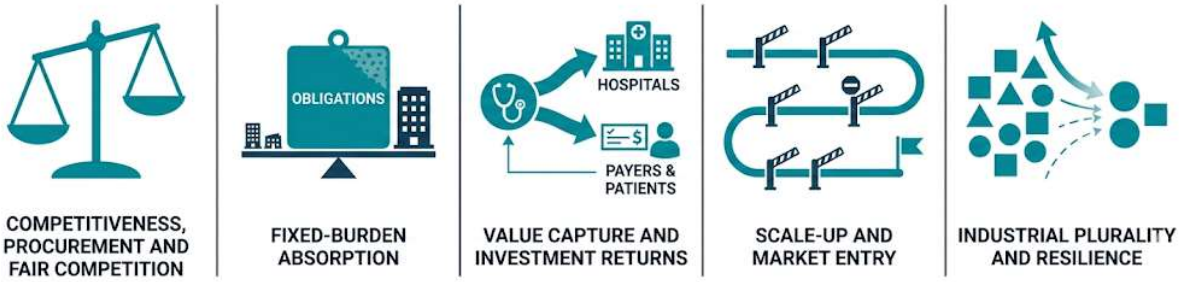
> Equal obligations can create unequal pressure across an asymmetric supplier base.

4 Five Structural Gaps Beyond Market Access

Europe retains substantial IVD leadership and industrial depth.

The five signs identified in Chapter 3 point to pressures beneath visible market continuity. These pressures do not indicate an absence of capability. They show where the foundations supporting Europe's position may require reinforcement.

The five structural gaps below describe where those pressures become industrially relevant.



	COMPETITIVENESS, PROCUREMENT AND FAIR COMPETITION	FIXED-BURDEN ABSORPTION	VALUE CAPTURE AND INVESTMENT RETURNS	SCALE-UP AND MARKET ENTRY	INDUSTRIAL PLURALITY AND RESILIENCE
Structural gaps	Procurement systems may reward incumbency, scale and price more readily than renewal	Regulatory, digital and evidence obligations impose minimum participation costs	Diagnostic value may accrue downstream without returning proportionately to suppliers	Innovation must cross regulatory, reimbursement, procurement and implementation gates	Supply continuity can coexist with concentration and reduced optionality
What it exposes	Competitive entry can weaken even while tenders continue to function	Smaller suppliers carry a heavier burden relative to revenue	Reinvestment capacity can weaken despite growing clinical use	Clinically relevant products may fail to become durable market positions	The market may remain supplied while the industrial base becomes narrower

> Product availability alone is an incomplete measure of industrial health. Leadership depends on the capacity to renew.

4.1 Competitiveness, Procurement and Fair Competition

A diagnostic market can remain operational while becoming harder to enter, contest and renew.[13]

Procurement systems are designed to secure continuity, control cost and reduce implementation risk. These objectives are legitimate. Installed platforms, trained staff, validated workflows and functioning service networks all favour stability.

The gap appears when stability begins to narrow realistic competitive pathways.

Procurement can remain functional	**While contestability weakens**
Tenders continue to be awarded	Participation costs rise
Existing platforms remain operational	Switching becomes harder
Prices remain disciplined	Differentiation receives limited recognition
Integrated suppliers meet broad service requirements	Smaller firms struggle to match bundled offers
Administrative procedures remain open	Selected tenders become impractical for specialist suppliers
Supply continuity is preserved	Renewal pathways narrow

The issue is not the presence of large manufacturers. They are essential to continuity and scale.

The issue is whether procurement leaves credible room for specialized and scaling suppliers alongside them. Smaller companies may withdraw from selected countries, tenders or clinical categories when the cost of participation becomes disproportionate to the realistic commercial opportunity.

A market may therefore remain formally open while becoming progressively less contestable. Products continue to reach laboratories, but the range of viable suppliers narrows.

> Fair competition requires more than procedural access. It requires credible pathways for entry, differentiation and renewal.

4.2 Fixed-Burden Absorption

The obligations required to remain active in the IVD market do not fall evenly across the supplier base.

Regulatory conformity, post-market surveillance, quality systems, software maintenance, cybersecurity controls, evidence generation and procurement administration all create fixed or semi-fixed participation costs. These obligations are necessary. But they do not decline when product revenue is modest or when market growth slows.[1928]

The structural gap lies in absorption capacity.

Obligations may be common	But the capacity to absorb it is not
Regulatory conformity and post-market surveillance	Large portfolios spread compliance costs across more products and revenue
Software maintenance and cybersecurity	Smaller suppliers may need additional external capability or disproportionate internal investment
Clinical evidence generation	Narrower portfolios carry less room to absorb lifecycle evidence costs
Quality systems and audit readiness	Minimum infrastructure is required regardless of company size
Tender administration	Participation costs can become material relative to the opportunity
Multi-country presence	Smaller firms are more likely to withdraw selectively from markets or categories

Large manufacturers can distribute these obligations across portfolios, geographies and dedicated specialist teams.

Smaller and specialized suppliers often face many of the same categories of cost with fewer products, narrower revenue bases and less organizational depth. Their burden is therefore not proportional to company size or product value.

The effect is gradual. Companies may delay entry, narrow portfolios, externalize critical functions or withdraw from selected geographies where the cost of participation exceeds the realistic commercial return.

This matters because smaller suppliers often preserve specialist capability, differentiated technologies and clinical niches that larger portfolios may not prioritize.

> Equal obligations can create unequal pressure across an asymmetric supplier base.

4.3 Value Capture and Investment Returns

Diagnostics creates value across healthcare systems, but much of that value is realized downstream.

Earlier decisions can reduce unnecessary treatment. Faster results can support better patient routing and earlier discharge. Companion diagnostics help identify the patients most likely to benefit from targeted therapies. Surveillance supports public-health response.

The supplier enables these outcomes, but typically captures only the price of the test, platform or service.

Value created by diagnostics	**Where the benefit appears**	**Typical supplier return**
Earlier clinical decisions	Patients, hospitals and payers	Test revenue under procurement pressure
Better routing and shorter delays	Hospitals and healthcare systems	Limited participation in operational savings
Therapy optimization	Patients, payers and pharmaceutical companies	Companion-diagnostic or assay revenue
Public-health readiness	Governments and populations	Contracted or public-sector revenue
Laboratory productivity	Laboratories and hospital networks	Platform, reagent or service revenue

This is not an argument that every downstream benefit should return to the supplier. Healthcare systems must protect affordability and reward efficiency.

The structural gap appears when the value retained by the supplier becomes insufficient to support the investment required for renewal.

That investment is continuous. Suppliers must finance new assays, platform development, clinical evidence, regulatory maintenance, software integration, cybersecurity, service networks and specialist teams. Capital remains committed across multiple institutional gates before returns become predictable.

Where expected returns remain weak or uncertain, investment may shift toward technologies, markets or geographies offering faster or more scalable returns.

> Diagnostics can create substantial healthcare value while remaining a difficult destination for long-duration capital.

4.4 Scale-Up and Market Entry

Europe generates diagnostic research, start-ups and specialist technologies. Only a limited number complete the crossing into durable clinical deployment.

A promising assay is not yet a functioning healthcare product. It must become standardized, clinically validated, compliant, reimbursed, procurable, scalable and supportable in routine use.[2]

The crossing requires several capabilities to be built in parallel.

Crossing stage	What must be secured	Where firms can stall
Development	Reliable assay design, scalable production and quality systems	Technical promise does not become a reproducible product
Regulatory authorization	Evidence, documentation and lifecycle compliance	Cost and timeline exceed available runway
Reimbursement recognition	Clinical and economic justification	Adoption remains delayed or uncertain
Procurement access	Tender readiness, differentiation and commercial credibility	Incumbency and bundled offers limit entry
Implementation	Training, service, workflow integration and support	Initial placements do not become durable use
Geographic expansion	Country-level access, distribution and institutional trust	Growth remains confined to a small number of markets

European regulatory approval does not remove commercial fragmentation. Reimbursement, procurement, laboratory organization and clinical practice still vary across countries. A supplier may secure EU-wide authorization and still face repeated national and institutional work before routine adoption is achieved.

The structural gap lies between invention and durable participation. Credible technologies may exist, yet companies can fail partway through the crossing because capital, organizational depth or market-access capacity proves insufficient.[17]

This matters because the loss is not always visible. The product may remain technically promising. The company may still exist. But the innovation does not reach the scale required to reinforce European diagnostic capability.

> Innovation does not renew an industry until it completes the crossing into routine clinical use.

4.5 Industrial Plurality and Resilience

Europe retains substantial IVD industrial capability. The question is how securely that capability is anchored and how easily it can renew.

Global participation is not itself a weakness. Non-European groups strengthen the European ecosystem through manufacturing, R&D, service, compliance and long-term support. European-headquartered groups also operate important capabilities outside the region.

The structural gap appears when product availability remains stable while the industrial depth behind it becomes harder to sustain.

Market can remain supplied	While industrial resilience weakens
Finished products continue to reach laboratories	Fewer firms retain the capacity to develop, adapt and renew them
Major platforms remain available	Specialist categories become more dependent on a limited number of suppliers
External trade remains positive	Upstream dependencies remain difficult to observe
Global companies continue to serve Europe	Local manufacturing, R&D and service depth may narrow
Procurement continues to function	Supplier plurality declines gradually
Shortages remain exceptional	Sourcing optionality becomes thinner before disruption occurs

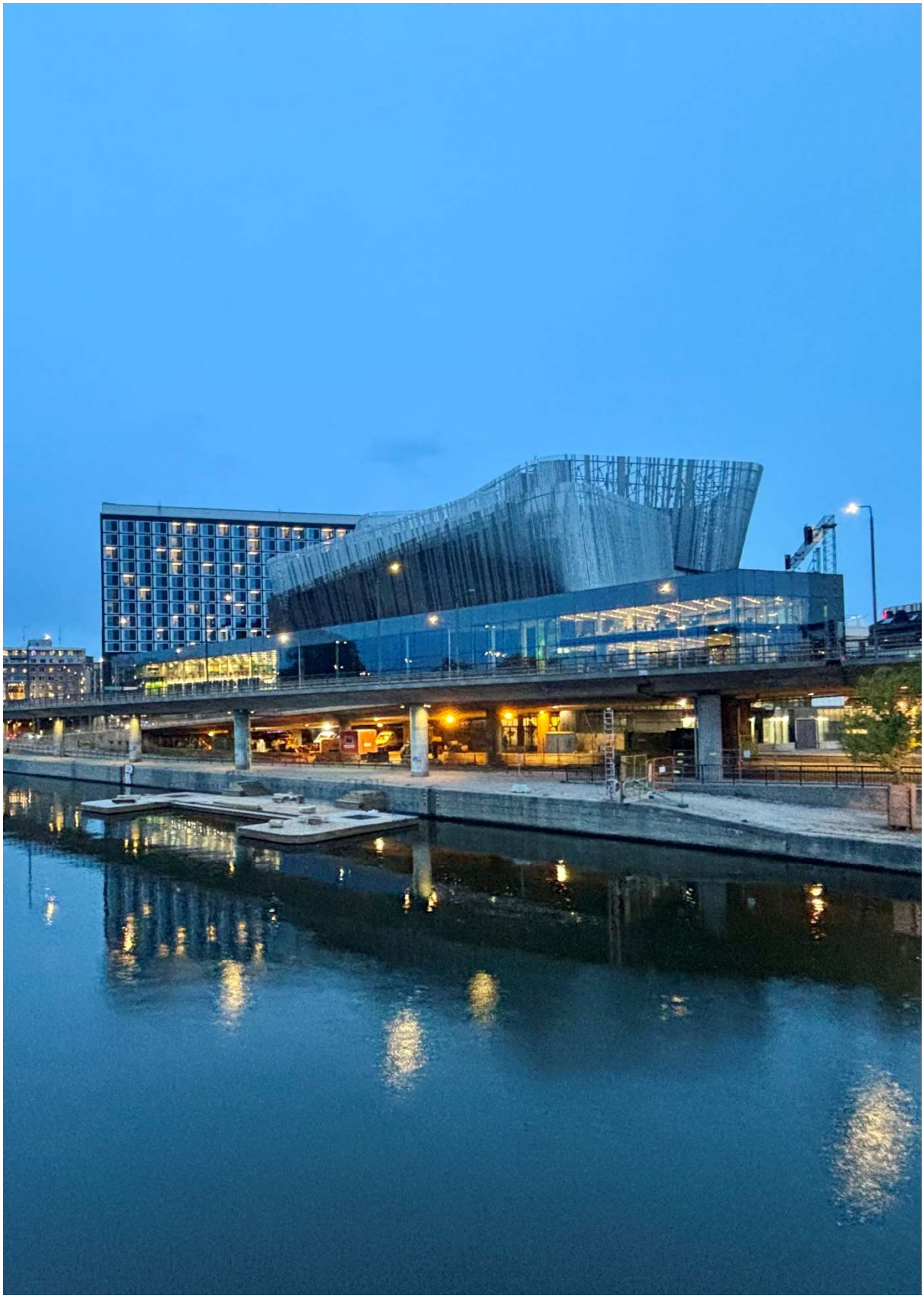
Europe's industrial strength is uneven. The Persodia Global Market Study indicates strong positions in several established categories, but weaker manufacturing depth in clinical genomics, professional POC, pathology and selected specialty segments.[6]

These signals do not prove product-level dependency. They identify where deeper analysis of manufacturing location, supplier concentration and sourcing resilience is required.

The less visible risk sits upstream. Diagnostics depends on biological materials, specialty chemicals, plastics, electronic components and precision substrates. Finished-goods trade data do not reveal the full structure of these dependencies. A positive trade balance in reagents and test kits can therefore coexist with vulnerabilities in the inputs required to manufacture them.

Resilience depends on more than access to products. It depends on supplier plurality, operating depth, manufacturing capability and sufficient sourcing optionality across the industrial chain.

> Resilience that is not visible in finished-goods data is also resilience that cannot be measured, defended or rebuilt until after it is lost.



Stockholm Waterfront — Europe’s diagnostics future is shaped where industrial capability, policy ambition and health-system expectation meet.

Epilogue

Europe has IVD capacity. Its renewal cannot be assumed.

Europe starts from a position of real industrial strength.

It has a substantial in-vitro diagnostics industry: manufacturers, service networks, installed systems, laboratory infrastructure and a positive trade position. European IVD capability is not captured by headquarters nationality alone. It is distributed across corporate groups, business units, manufacturing sites, R&D centres and service networks operating across borders.

The issue is whether Europe can sustain that capacity over time.

The pressure is becoming visible.

A market can remain supplied while the industry behind it becomes harder to renew.

Modern healthcare expects more from diagnostics: earlier clinical decisions, more efficient care delivery, precision medicine, public-health readiness and integration into increasingly demanding digital and regulatory environments.

At the same time, the industry remains only partially visible. A reporting framework that captures only part of the industry's economic scale weakens the visibility of its contribution and limits the quality of the debate around its future.

Five signs of pressure are becoming visible. The established reporting segment represents a progressively smaller share of healthcare expenditure. Inflation absorbs much of nominal growth. Diagnostic use can rise without proportionately strengthening supplier economics. Capital takes longer to return. Regulatory, digital and evidence obligations fall unevenly across companies of very different scale.

None of these signs indicates immediate failure. Together, they suggest that the conditions required for renewal are becoming less secure.

What is at stake?

The risk is not sudden failure. It is the gradual loss of industrial depth.

This loss develops incrementally: smaller companies withdraw from selected categories; specialist capabilities become uneconomic; innovation fails to reach routine clinical deployment; effective competition narrows; manufacturing and service capacity become more concentrated.

Products may still reach the market. Laboratories may still operate. Procurement may still function.

Yet the system becomes less plural, less adaptive and more dependent on a smaller number of industrial actors and locations.

Europe has IVD capacity. Preserving it requires the conditions that allow the industry to invest, renew, scale and remain sufficiently plural over time.[12]

> Surface continuity is visible.
> Structural continuity must be built.

Annexes

Annex 1 — Data Perimeter and Core Definitions

The Persodia Global Market Study uses a broader commercial diagnostics perimeter than the MedTech Europe reported series. It includes instruments, reagents, consumables, software, automation and related services used in diagnostic pathways across laboratories, professional point-of-care settings and consumer channels. Consumer diagnostics, including continuous glucose monitoring, and selected clinical-use shares of sequencing and mass-spectrometry platforms are included.

Research-use-only products, drug-discovery tools, general laboratory equipment without a diagnostic claim and downstream laboratory-testing services are excluded.

The Global Market Study figures for Europe refer to the study's wider **continental-Europe** perimeter. They are not directly equivalent to the narrower **EU27+** perimeter used for the MedTech Europe and healthcare-expenditure comparisons in Chapter 3 and Annex 2.

Term	Definition used in this monograph
EU27+	The EU27, EFTA and the United Kingdom. This is the default European perimeter unless a narrower perimeter is specified.
MedTech Europe market estimate	Standardized reported IVD-market sales consolidated by MedTech Europe through national industry-association and GDMS channels. It is used as the anchor for the European supplier-participation analysis.
Persodia modeled regional sales	Regional demand estimate derived from the broader Persodia Global Market Study. It includes selected diagnostic, workflow and adjacent categories and is not directly equivalent to the MedTech Europe estimate.
Mapped physical manufacturing	Directional product-level estimate of physical production location. It is not audited plant output, value added or trade balance.
European manufacturer base	Manufacturers located within EU27+, independently of group-headquarters location or capital ownership.
HS 382200 trade proxy	External-trade proxy covering diagnostic and laboratory reagents and medical test kits. It is not equivalent to the total IVD market and does not capture the full value of instruments, software, services or upstream inputs.
Clinical-laboratory patient episode	Diagnostic act associated with a sampling date and time. It is not a count of unique patients or individual assays. One episode may include several tests.
Adjusted IVD CAGR	Reported IVD CAGR after applying a documented consolidation sensitivity adjustment. It is a directional working estimate, not an audited accounting measure.

Annex 2 — European IVD Market Growth and Supplier Participation

This annex provides the quantitative basis for the supplier-participation analysis developed in Chapter 3.

The comparison uses the MedTech Europe reported-market series for the European IVD sector and total current healthcare expenditure across the EU27, EFTA and the United Kingdom. All figures are stated in current euros.

The MTE-reported series is the only consistent published European-perimeter IVD series covering the full reference period. It represents the established association-reporting segment of the industry rather than the full diagnostics economy. Broader Persodia modelling indicates that the wider European market is materially larger. The findings below should therefore be read as structural indicators for the MTE-reported segment.

Long-run participation in healthcare expenditure

The MTE-reported IVD market has represented a progressively smaller share of total current healthcare expenditure across every observed anchor period.

Anchor year	MTE-reported IVD market, €m	Current HC expenditure, €m	IVD / HCE	Change versus prior anchor
2009	10,685	1,344,789	0.795%	—
2014	10,635	1,413,220	0.753%	−0.042 pp
2019	11,265	1,683,278	0.669%	−0.083 pp
2023	13,315	2,204,234	0.604%	−0.065 pp
2024E	13,448	2,357,581	0.570%	−0.034 pp

Source: Persodia Research. Technical Note — Analytical Foundations and Data Audit: Monograph No. 3, Chapter 3 / Annex 2. 2026.

The ratio declined across every observed anchor period. The confirmed-endpoint decline from 2009 to 2023 is approximately **24%** in relative terms. Including the directional 2024 estimate, the decline reaches approximately **28%**.

Method note. The 2009 healthcare-expenditure value is a Persodia backcast from the published 2010 value. The 2024 row is a directional estimate and should not be treated as a confirmed anchor year. The 2014 participation ratio uses the report-vintage healthcare-expenditure value published alongside the IVD figure to preserve internal consistency at that anchor point.

Growth relative to healthcare expenditure

For the 2014–2023 CAGR comparison, healthcare expenditure is calculated on a consistent direct-source SHA basis at both endpoints.

Measure	Nominal CAGR, 2014–2023
MTE-reported IVD market	2.53%
Current healthcare expenditure	4.38%
Reported gap versus healthcare expenditure	−1.85 pp
Central consolidation-adjusted IVD scenario	3.68%
Central adjusted gap versus healthcare expenditure	−0.70 pp

The MTE-reported IVD segment grew approximately 1.9 percentage points per year more slowly than healthcare expenditure over 2014–2023.

A central sensitivity scenario allowing for consolidation-related purchasing and pricing effects narrows the gap to approximately 0.7 percentage points, but does not remove it. This adjustment is directional and should not be interpreted as an audited correction.

Real growth after inflation

Measure	Nominal CAGR, 2014–2023	Inflation proxy	Real CAGR
MTE-reported IVD market	2.53%	2.66%	−0.13%
Central consolidation-adjusted scenario	3.68%	2.66%	+0.99%

Source: Persodia Research. Technical Note — Analytical Foundations and Data Audit: Monograph No. 3, Chapter 3 / Annex 2. 2026.

In real terms, the reported IVD segment was broadly flat over the period. The central sensitivity scenario indicates limited positive real growth.

Interpretation

The participation-ratio decline and the CAGR gap point in the same direction: the established MTE-reported segment of the European IVD industry has not participated proportionately in the expansion of the healthcare systems it supports.

These findings do not describe the full diagnostics economy. Broader market modelling captures categories that are incompletely represented in the MTE series, including consumer diagnostics, clinical genomics, pathology capital equipment, laboratory informatics, sampling infrastructure and revenues from smaller or non-European manufacturers. On that wider perimeter, the participation gap narrows materially.

The structural conclusion remains relevant: supplier renewal cannot be inferred from current product availability alone.

Sources and methodology

IVD-market values are drawn from published EDMA and MedTech Europe European IVD market-statistics reports.

Healthcare-expenditure values are drawn from the Eurostat System of Health Accounts series and aligned UK and EFTA sources. The 2014–2023 CAGR comparison uses a consistent direct-source SHA basis. The 2023 EU27 value remains provisional and should be refreshed if revised before publication.

The consolidation-adjusted scenario and broader-market comparison are Persodia Research analytical estimates.

A detailed source chain, methodological rationale and audit trail are available in: Persodia Research. Technical Note — Analytical Foundations and Data Audit: Monograph No. 3, Chapter 3 / Annex 2. 2026.[9]

Annex 3 — Capital Duration and Consolidation Methodology

Capital-duration stack

IVD innovation requires capital to cross multiple institutional gates before a return becomes visible. Product development, regulatory authorization, evidence generation, reimbursement recognition, procurement, implementation and post-market obligations follow separate timelines.

Institutional gate	Capital effect	Industrial exposure
Development and regulatory authorization	Investment before revenue; delayed market entry	Upfront R&D, validation and regulatory cost
Clinical evidence and reimbursement	Multi-year cost before adoption; uncertain revenue recognition	Evidence-generation burden and payer uncertainty
Procurement and implementation	Long sales cycle; delayed installed-base growth	Working-capital exposure, training and integration cost
Post-market obligations	Permanent cost after launch	Surveillance, quality, software and evidence requirements
Platform renewal	New investment before the previous cycle is fully recovered	Reinvestment pressure across overlapping product generations

The stack is illustrative rather than a measured sector average. Its purpose is structural: to show how multiple institutional gates extend the interval between investment and return.

Central consolidation scenario

The consolidation model estimates the potential supplier-revenue effect of large laboratory groups purchasing a share of national IVD supply under sustained tender-pricing pressure.

Central scenario input or output	Value
Tracked-cohort laboratory-group revenue	EUR 8.40bn
Assumed IVD purchasing ratio	15%
Implied purchasing value	EUR 1.26bn
Assumed tender-pricing erosion	10%
Implied annual supplier-revenue suppression	EUR 126m (selected ref period)
Suppression correction applied to reported CAGR	+1.15 percentage points
Reported European IVD nominal CAGR	+2.53%
Central adjusted European IVD nominal CAGR	+3.68%

Source: Persodia Research. Technical Note — Analytical Foundations and Data Audit: Monograph No. 3, Chapter 3 / Annex 2. 2026. Persodia Research. European Market Study. Internal analytical study, 2026.

Methodology note.

The central consolidation scenario is a directional sensitivity model, not an audited counterfactual.

The correction is calculated as: laboratory-group revenue × assumed IVD purchasing ratio × assumed tender-pricing erosion ÷ European IVD market value.

The tracked cohort includes countries for which historical market data and laboratory-group estimates are available. The resulting suppression rate is extrapolated to the European aggregate.

The scenario should be used to illustrate the potential scale of consolidation-related pressure, not as a precise estimate of lost revenue.

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Analytical Grounding

The structural analysis in this monograph draws on the conceptual framework developed in *Inside the Clinical Diagnostics Industry: Constraints Shaping Strategy — Towards Health Intelligence*. Concepts operative throughout this text are applications of that broader framework to the present European industrial question.[1]

Clinical and policy observations are drawn from structured review of public institutional materials, public industry sources, and ongoing observation of diagnostics and medtech industry dialogue. In particular, MedTech Forum Stockholm 2026 provided a timely observational context for the final framing of this monograph, especially around European competitiveness, regulatory burden, digital transformation, health-system resilience and the evolving strategic role of diagnostics.

Additional conference observations and professional exchanges, including those from Analytica, ECCMID and MedTech Europe Forum settings, informed the analytical framing but are not listed as formal references unless tied to specific public materials.

Where market calculations are introduced, these combine publicly available industry data with Persodia Research's proprietary comparative synthesis.[569]

Demand-side indicators used in this monograph — laboratory service expenditure, reimbursable medical-biology expenditure and laboratory-group test volumes — are not direct equivalents of IVD supplier revenue. They are used only to assess whether weak supplier revenue growth reflected weak diagnostic utilization or a decoupling between utilization growth and supplier revenue capture.

About the Author

Miguel Oliveira is a senior practitioner and analyst of the in-vitro diagnostics industry. He is the founder of Persodia Research, an independent research programme dedicated to the structural analysis of the IVD industry, based at persodia.org.

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Colophon

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