

European IVD Market Statistics

Report 2011



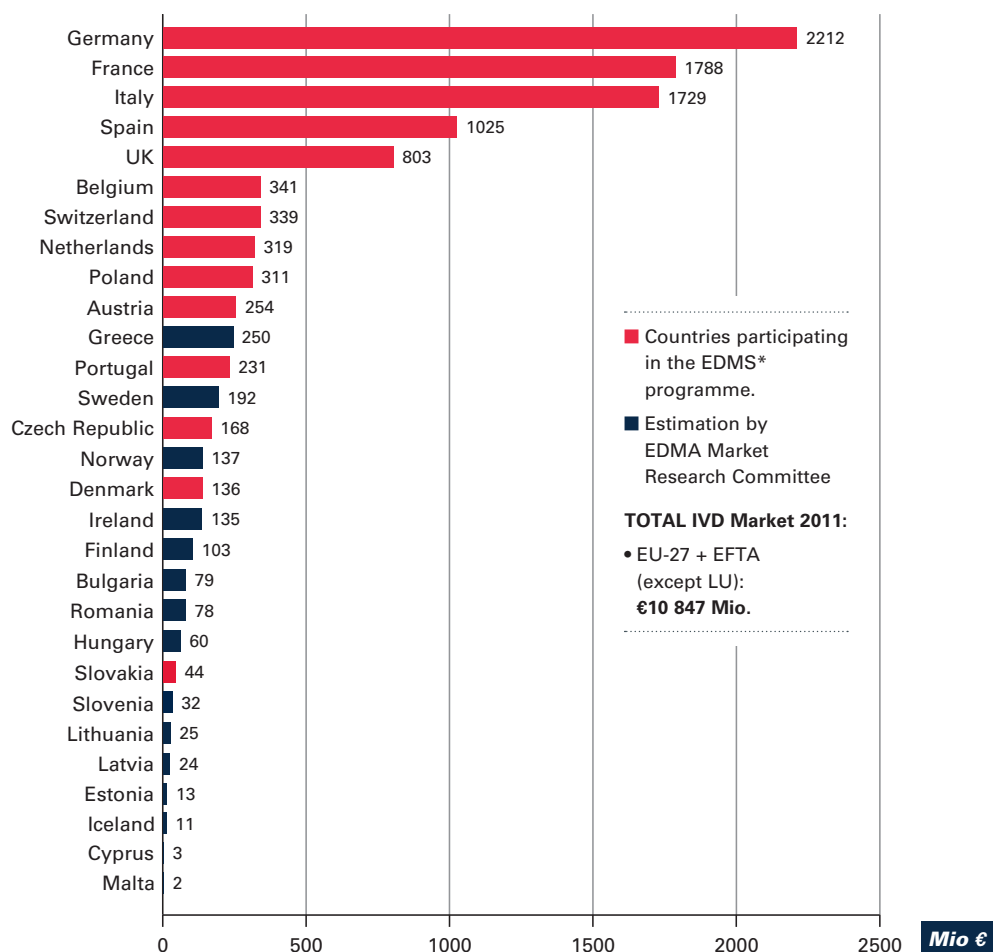
OVERVIEW

The European Diagnostic Manufacturers Association, EDMA, is pleased to publish the market estimates of the In Vitro Diagnostic industry in Europe, for the year 2011. The EDMA figures include macroeconomic and healthcare expenditure data for all 27 Member States, as well as for the European Free Trade Association (EFTA) members.

In vitro diagnostics (IVDs) are an essential part of today's healthcare. IVDs are used to diagnose, monitor, screen and assess predispositions to diseases, thereby contributing to much of the available medical information regarding a patient. By allowing earlier and more targeted treatments, IVDs help to reduce hospital stays and convalescences, resulting in a healthier population and economic growth in the long run.

The overwhelmingly positive potential of IVDs in the context of cost-effective and patient-friendly healthcare tends to fall off the radar. In fact, despite the benefits that they offer, the IVD market revenues of €10.8 billion generated by the industry in Europe only accounts for 0.8% of the total healthcare expenditure (THE).

European IVD market 2011 (million €)



*EDMS = European Diagnostic Market Statistics

OVERVIEW

2011 Market Statistics

Countries	Population	GDP	GDP / capita	THE	THE / capita	THE as % GDP	IVD mkt. 11	IVD mkt.10*	IVD mkt. growth rate 10-11	IVD mkt. / THE	IVD mkt. / capita
	Thousands	Mio €	€	Mio €	€	%	Mio €	Mio €	%	%	€
Source WHO 2010							Source EDMA				
Germany	81,757	2,476,800	30,295	288,177	3,525	11.6%	2,212	2,149	2.9%	0.8%	27.1
France	64,848	1,932,802	29,805	229,682	3,542	11.9%	1,788	1,795	-0.4%	0.8%	27.6
UK*	61,990	1,681,231	27,121	161,995	2,613	9.6%	803	765	5.0%	0.5%	13.0
Italy	60,468	1,556,029	25,733	148,276	2,452	9.5%	1,729	1,724	0.3%	1.2%	28.6
Spain	46,073	1,051,342	22,819	100,284	2,177	9.5%	1,025	1,045	-1.9%	1.0%	22.2
Netherlands	16,612	588,414	35,421	70,153	4,223	11.9%	319	316	1.0%	0.5%	19.2
Greece	11,305	227,318	20,108	23,297	2,061	10.2%	250	275	-9.0%	1.1%	22.1
Portugal	10,637	172,799	16,245	19,007	1,787	11.0%	231	258	-10.5%	1.2%	21.7
Belgium	10,883	354,378	32,563	37,949	3,487	10.7%	341	340	0.3%	0.9%	31.3
Sweden	9,378	366,229	39,052	35,281	3,762	9.6%	192	187	2.7%	0.5%	20.5
Austria	8,388	286,197	34,120	31,402	3,744	11.0%	254	249	2.0%	0.8%	30.3
Denmark	5,546	235,509	42,465	26,883	4,847	11.4%	136	134	1.2%	0.5%	24.5
Finland	5,363	180,253	33,610	16,135	3,009	9.0%	103	100	3.0%	0.6%	19.2
Ireland	4,476	155,992	34,851	14,334	3,202	9.2%	135	131	3.1%	0.9%	30.2
Luxembourg	507	40,267	79,422	3,129	6,172	7.8%	-	-	-	-	-
EU-15	398,231	11,305,560	28,389	1,205,984	3,028	10.7%	9,519	9,469	0.5%	0.8%	23.9
Poland	38,187	345,443	9,046	25,773	675	7.5%	311	285	9.1%	1.2%	8.1
Romania	21,431	123,502	5,763	6,890	321	5.6%	78	75	4.1%	1.1%	3.6
Czech Rep	10,518	153,803	14,623	12,112	1,152	7.9%	168	167	0.9%	1.4%	16.0
Hungary	10,000	96,292	9,629	7,054	705	7.3%	60	57	5.1%	0.9%	6.0
Bulgaria	7,534	36,062	4,787	2,477	329	6.9%	79	77	2.5%	3.2%	10.4
Slovakia	5,430	65,887	12,134	5,792	1,067	8.8%	44	45	-2.2%	0.8%	8.1
Lithuania	3,287	27,595	8,395	1,943	591	7.0%	25	25	1.0%	1.3%	7.7
Latvia	2,239	18,112	8,089	1,211	541	6.7%	24	24	0.5%	2.0%	10.9
Slovenia	2,049	35,416	17,285	3,333	1,627	9.4%	32	31	4.0%	1.0%	15.8
Estonia*	1,340	13,762	10,270	932	695	6.8%	13	13	2.0%	1.4%	10.1
Cyprus	804	17,334	21,560	1,034	1,286	6.0%	3	3	2.0%	0.3%	3.9
Malta	416	6,164	14,817	533	1,281	8.6%	2	2	2.5%	0.4%	5.1
EU-27 (EU-15 + new MS)	501,466	12,244,922	24,418	1,275,067	2,543	10.4%	10,360	10,274	0.8%	0.8%	20.7
Switzerland*	7,786	447,444	57,468	51,555	6,622	11.5%	339	336	1.0%	0.7%	43.5
Norway	4,889	323,806	66,231	30,683	6,276	9.5%	137	128	7.0%	0.4%	28.1
Iceland	318	9,560	30,064	899	2,826	9.4%	11	11	-1.0%	1.2%	33.8
TOTAL (EU-27 + EFTA)	514,459	13,025,732	25,319	1,358,205	2,640	10.4%	10,847	10,748	0.9%	0.8%	21.1

* The applied exchange rates are the 2011 annual average exchange rates published by Oanda (www.oanda.com). Applying a single exchange rate to both 2010 and 2011 sales data eliminates possible fluctuations of market size and market growth due to exchange variations.

* During the data collection of 2011 year's figures the 2010 market size was re-estimated at the same time. That, together with the use of a single exchange rate, explains why some countries show different revenues compared to the figures presented in last year's report for 2010. The growth rate between 2010 and 2011 has been calculated using the re-estimated figures. Greece and Slovakia show considerably higher 2010 re-estimates. Slovakia recently joined the EDMS programme and therefore now provides a more complete picture of the IVD market. For Greece, IVD products for self-testing have been included in the new estimates.

* The data regarding population, GDP and healthcare expenditure are from the World Health Organisation (WHO). Reports from earlier years have used data from OECD.

* UK data does not reflect the market share of companies which do not participate in EDMS.

* Estonian GDP and THE data are 2009 year's figures from Eurostat.

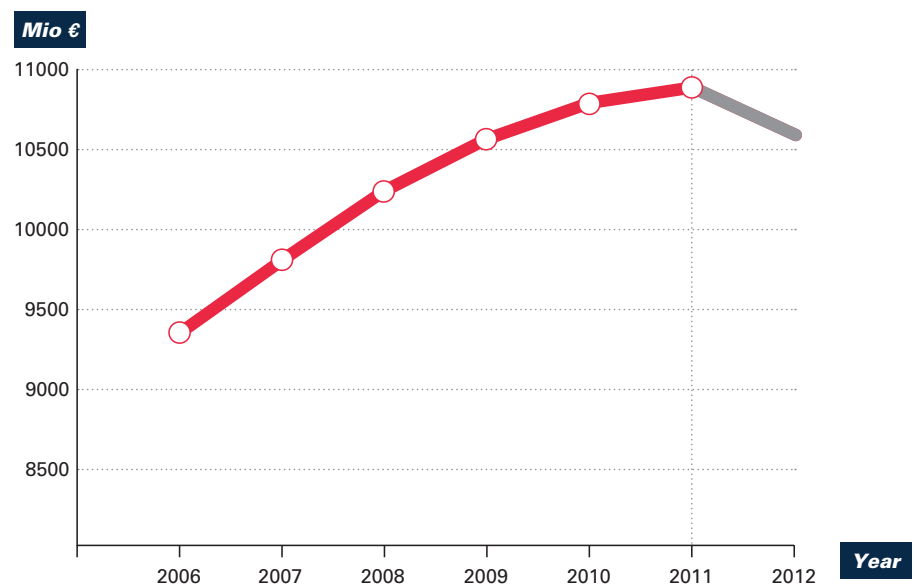
* Swiss data include Lichtenstein.

OVERVIEW



The economic recession in Europe has affected the IVD market, particularly in Greece and Portugal, which is reflected in the moderate overall market growth of 0.9% from 2010 to 2011. This is significantly lower compared to the previous five years, which saw growth of around 2-4% annually. Negative trends are expected to continue for 2012 and a decline of the European IVD market in the range of -2% to -3% is anticipated.

European IVD Market Revenues (million €)

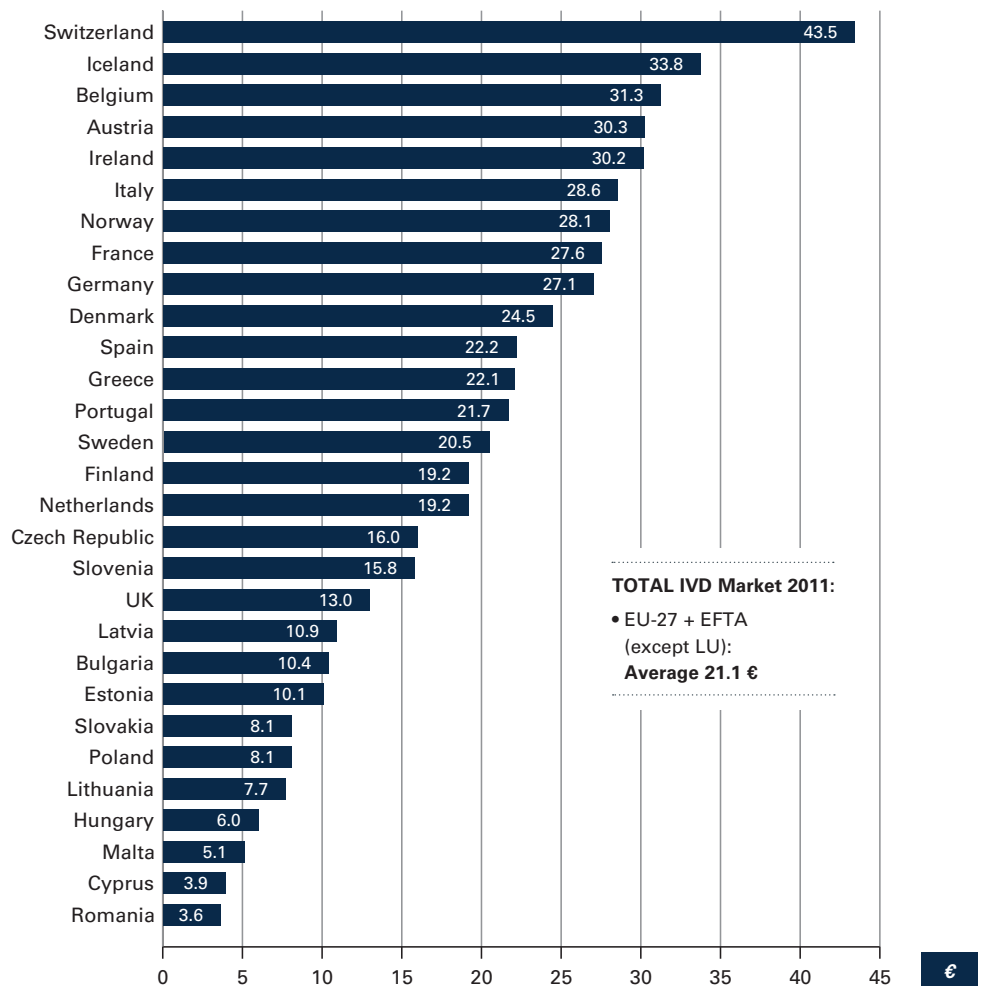


In the wake of the recession a number of actions have been put in place to reduce public healthcare spending. These include a reduction in the number of reimbursed tests and consolidations of laboratories. Not only have these measures had a negative impact on the IVD market, but importantly they also risk to threaten the health of patients. Another consequence of the recession is the ability of governments to pay their debts to the IVD suppliers. Late payments pose a major challenge to IVD suppliers in countries affected the most by the economic recession, such as Greece, Italy, Portugal and Spain.

COUNTRY-SPECIFIC DATA

Variances in the IVD market are visible on a country-by-country basis. This is a reflection of not only the different levels of emphasis in individual public health programmes, but also of a lack of uniform reimbursement procedures and the degree of impact that the euro crisis has had on the overall state of the national economy. Patients from different European countries have unequal access to IVDs as the resources spent on IVDs varies substantially, from €3.6 to €43.5 per capita per annum. The average stands at €21.1 for EU+EFTA countries.

IVD per capita (€)





GERMANY - FRANCE DATA

Germany

In 2011, Germany maintained its position as the largest European IVD market, preceding France and Italy. Due to a strong last quarter the total market growth ended at 2.9% after two years of stagnation and a slight decrease of revenues.

The glucose self-testing market recovered from negative growth in 2010 and total lab reagents revenues increased by 2.0%. The continuing price decrease of IVDs prevents more favourable growth rates and it is still unclear whether 2011 growth will continue in 2012.



France

The implementation of the Clinical Biology Reform (Ordinance No. 2010-49) on 13 January 2010 brought about the accelerated consolidation of private clinical laboratories. According to the French Health Regulatory Agency (ANSM), from the original 4000 laboratories, 1650 disappeared within 18 months. These consolidations contributed to maintaining pressure on selling prices and slowing down IVD activity in France.

New government policies have also had an impact on the IVD industry as changes in legislation brought forth new direct and indirect constraints. For example, on 25 February 2011 the reimbursement rules for diabetes self-testing strips were amended to only cover the reimbursement of 200 strips per patient with type 2 diabetes per year. The restriction has had a severe impact on this market segment, contributing to a 6.7% decline since its enactment.

This reduction is added to an earlier decision by the French Public Health Insurance (UNCAM) dating from January 2010, which have resulted in further changes to the reimbursement procedures of 150 acts of Clinical Biology (JO_20110111). Many of these are high volume tests such as thyroid-stimulating hormone (TSH) test (-10%), C-reactive protein (CRP) test (-5%) and glycosylated hemoglobin (HbA1c) test (-20%). The UNCAM decision slowed down activity in the French laboratory market in general and for IVDs, the market decrease reached -0.4% in 2011.



THE: Total Healthcare Expenditure
GDP: Gross Domestic Product

ITALY - SPAIN DATA

Italy

Revenue growth in Italy amounted to 0.3%. Both the public hospital and the private laboratory markets are facing measures to restrain healthcare costs and centralise purchasing. The situation of late payments and difficulties in bank financing are still critical issues, in particular for SMEs.



Spain

As a consequence of the economic crisis there is a decline in hospital activity across Spain. This has led to extreme price pressures due to aggregated purchasing and a longer duration of tender processes – currently up to four years – that are often going to very few providers. The definitions of geographical areas, which have been redefined from encompassing single hospitals to entire regions and thus including several hospitals, has also had a negative impact on the IVD industry.

In already unfavourable growth circumstances, tight regulatory control and strict IVD protocols further restrict the market, which dropped by 1.9% in 2011. Even worsening the Spanish situation is the increasing debt of the public healthcare providers to the IVD suppliers. Late payments pose a major challenge to the Spanish IVD market.



THE: Total Healthcare Expenditure
GDP: Gross Domestic Product



UK - SWITZERLAND DATA

United Kingdom

Though the UK government is investigating the possibility of creating a reimbursement model for diagnostics, this has not yet been settled or implemented. Even without this in place, the IVD market grew, as expected, by 5.0% in 2011. The increase was gradual and consistent, with each quarter showing an increase on the previous.

The continuation of the growth in 2012 is debated as the National Health Service (NHS) is undergoing a number of changes in line with the overall target to reduce the pathology laboratory budget by £500m. Yet the increase in 2011 shows that IVDs are still valued and that savings will likely be made through consolidation of staff and premises costs, rather than a reduction in testing.

A significant reduction of about 10% in sales of instruments and consumables is likely the result of a shift to purchasing based on reportable results and the use of managed service contracts instead of capital sales. Meanwhile, the exception in microbiology is a response to the introduction of new automated technologies.



Switzerland

Due to reduced rates of reimbursement, the number of IVD tests performed in doctors' offices is declining and testing activities are being transferred to commercial laboratories. Such commercial laboratories are subject to and impacted by mergers and acquisitions, which results in fewer customers to serve and additional pressure on pricing. Overall, the Swiss IVD market showed a moderate growth of 1.0% in 2011.



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POLAND - GREECE DATA

Poland

The total 9.1% growth of the Polish IVD market is due to a very high demand for glucose strips in the fourth quarter of 2011. The increase of glucose strip revenues is estimated to be around 19% compared to 2010 and is the result of expected changes in the reimbursement regulations due to emerge in January 2012. The market growth for laboratory IVDs was 2.0%.



Greece

The recession in Greece reached 7% in 2011, while the IVD market dropped by 9.0% compared to 2010.

In January 2011, IVD manufacturers received state bonds instead of due payment for supplies provided to public hospitals as far back as 2007 (equaling a delay of 1400 days). However, they were forced to waive all interests that had accumulated on the outstanding debt. The bonds would have matured in 2011-2013, but became subject to a drastic cutback under the second bailout package for Greece in early 2012, resulting in an actual loss of 80% of the face-value for the suppliers. Nevertheless, the suppliers were required to pay VAT to the state on the entire amount that was originally invoiced. As a consequence, the liquidity of companies was deeply compromised, especially as the bonds had been utilised as collateral to ensure access to credit.

A series of changes were introduced by the Greek government in 2011 to further reduce the public health expenditure in general and spending on IVDs in particular. The main criterion for the procurement of IVDs has always been the lowest price, not the overall value of the products. This tendency was further aggravated by the creation of the so-called Observatory of Prices in 2011, which sets price caps regardless of technical specifications, volumes, method, reagent rental on tenders and contracts. This cost-containing mechanism even applies retrospectively for 2010 invoices. In the meantime, the bad practice of late payment continues (average 410 days sales outstanding [DSO] at the end of December 2011).

In the future, centralised and e-procurement are expected to become of greater importance and the relevant legal framework has already been established. Public hospital mergers are also ongoing which aims to reduce their number from 131 to 80. This has led to layoffs and a 30% reduction in the number of public hospital beds. The recession has also taken its toll on the private healthcare sector, where financial constraints have resulted in less investment and increased price pressure.



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PORTUGAL - HUNGARY DATA

Portugal

In 2011, the Portuguese IVD market experienced a double-digit decline in revenue. Even with a 10.5% loss for 2011, the market is likely to suffer more as austerity measures are implemented. The significant public budget deficit – of which healthcare is one of the biggest contributors – has resulted in some dramatic measures that have, in turn, had a tremendous impact on the industry. The revision and reduction of the list of reimbursed tests, combined with decreased reimbursement levels and the execution of electronic prescription processes led to significant declines, especially in the second half of 2011.

Yet the most crucial challenge for the diagnostics industry in Portugal is still the issue of late payments. The national average for the delay has reached more than 500 days, an increase of over 60% in 2011. With almost sole focus on pricing and poor attitudes toward payment within the healthcare system, it has become more and more difficult for the IVD industry to introduce available innovation to improve the quality of patient treatment and clinical decision making.

Concentration and consolidation trends remain visible on the market and reforms have been announced in the memorandum of understanding (with the “Troika”), with several steps expected to get underway over the forthcoming months. The outlook for the near future remains negative with continuous revenue decline and no definite statement from the Ministry of Health about the recovery of the debt situation.



Hungary

A cap was approved in the annual budget for the reimbursement of laboratory tests in 2002, and the nominal figure has been the same since. The unfavourable shift in the exchange rate from the HUF, as well as the rising cost of labour and energy reduced the share reserved for reagents in the fixed budget.

The growth of 5.1% was derived from sales taken outside the reimbursement system. It includes self-tests as well as private laboratory services.



THE: Total Healthcare Expenditure
GDP: Gross Domestic Product



2012 IVD Outlook

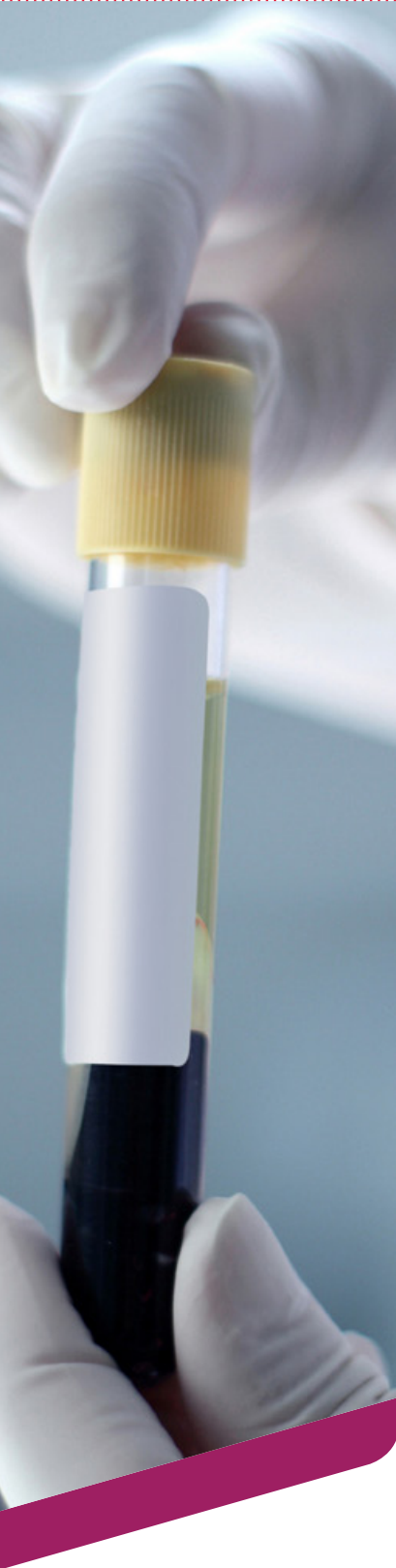


According to the IVD industry flash report – the Management Information System (MIS) - the European IVD market will come out with a negative figure for 2012. Until September 2012, the revenue decline was -2.7% when compared to 2011. Double digit market declines are experienced in Greece, Poland and Portugal, but also other countries, including Germany, France, Italy and Spain, are seeing single digit declines.

IVD suppliers interested in learning more about the MIS programme, please visit www.edma-ivd.eu/about-in-vitro-diagnostics/market-intelligence



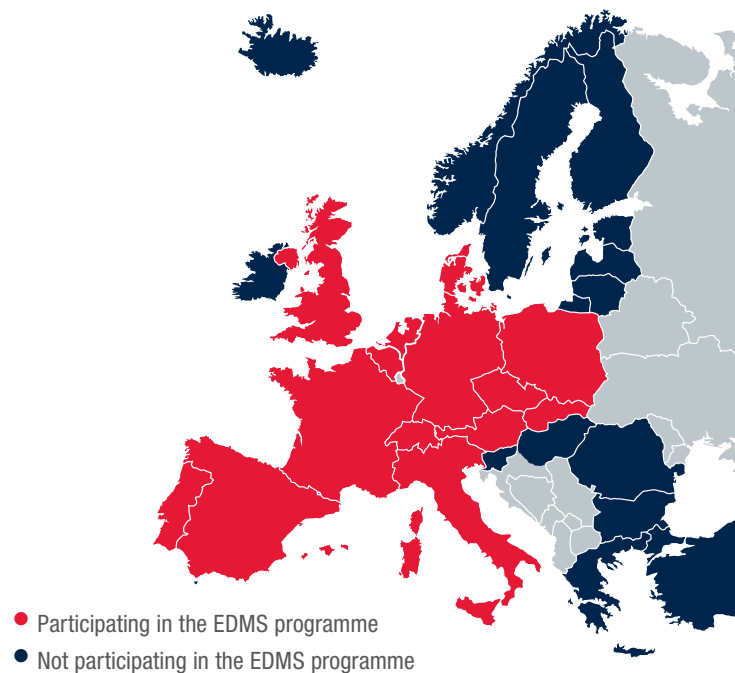
DATA GATHERING



The results presented above are based on individual estimates made in 29 European countries and EFTA:

- 14 countries participating in the European Diagnostic Market Statistics (EDMS) programme: *Austria, Belgium, Czech Republic, Denmark, France, Germany, Italy, the Netherlands, Poland, Portugal, Slovakia, Spain, Switzerland, and the UK.*
- The National Association Members of EDMA and the EDMA Market Research Committee have estimated the IVD market in 15 other countries not participating in the EDMS programme: *Bulgaria, Cyprus, Estonia, Finland, Greece, Hungary, Iceland, Ireland, Latvia, Lithuania, Malta, Norway, Romania, Slovenia, and Sweden.*

14 countries participating in the European Diagnostic Market Statistics (EDMS) programme



The EDMA figures per country are compiled from the European Diagnostic Market Statistics (EDMS) programme, through which companies report invoiced sales of reagents, instruments and consumables to an independent auditor, CIP, as based on the Global IVD (former EDMA) Classification. This is done in association with the EDMA Market Research Committee and the National Association Members of EDMA.

More than 85% of the market is covered in major countries by EDMS, ensuring the reliability and objectiveness of the information provided by EDMA and its members. EDMA encourages all IVD suppliers and countries to participate in the EDMS programme, which is the largest in vitro diagnostic audit in Europe and the most accurate source of information for understanding and predicting market trends.



IN VITRO DIAGNOSTICS



About In Vitro Diagnostics

In vitro diagnostics (IVDs) are non-invasive tests performed on biological samples (for example blood, urine or tissues) to diagnose or exclude a disease. IVDs provide valuable information about how the body is functioning and the state of health. They are used for diagnosis, screening and therapeutic monitoring of diseases. IVDs have a broad scope ranging from sophisticated technologies performed in clinical laboratories to simple self-tests, such as those for pregnancy and glucose monitoring.

About EDMA

EDMA, the European Diagnostic Manufacturers Association, advocates for the interests of the in vitro diagnostic industry and its enormous contribution to transforming healthcare systems by improving healthcare efficiency and reducing costs. EDMA's strength lies in its close co-operation with European institutions, patients groups, trade associations, health professionals, and academia, working together to shape the EU policy that will have the most impact on the lives of Europeans and reinforce the European IVD industry's voice globally. From small businesses to major corporations, the European in vitro diagnostic industry is a market worth around 11 billion euro. Driven by research and development, 95% of the industry is comprised of small and medium size enterprises and approximately 1 billion euros per year is reinvested in R&D. For more information, visit www.edma-ivd.eu.

For more information

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