

European **IVD** **Market** Statistics

Report 2014





OVERVIEW



The European Diagnostic Manufacturers Association, EDMA, is pleased to publish the market estimates of the In Vitro Diagnostic (IVD) industry in Europe, for the year 2014. The EDMA figures include macroeconomic and healthcare data for all 27 member states, as well as the European Free Trade Association (EFTA) members. As in the 2013 report, data from Turkey are included.

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 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, reduced costs and economic growth in the long run.

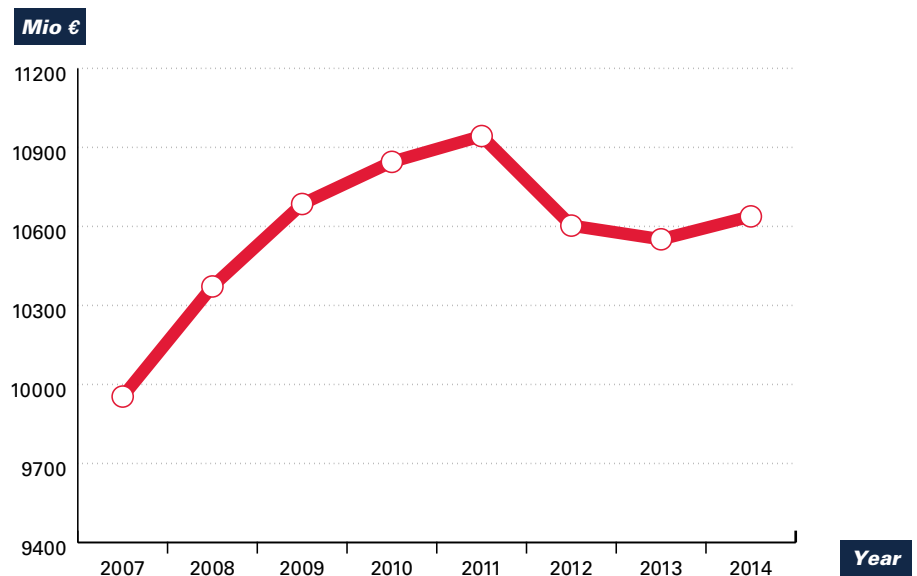
Despite stagnating or decreasing revenues in four of the five largest European IVD markets (the UK being the exception), overall revenues across EU-27 plus EFTA increased by 0.8% to €10,635 million, reversing recent trends. However, this remains below the revenues recorded in 2009 (€10,685).

OVERVIEW



While German IVD revenues stagnated overall, modest growth was seen in both microbiology (+5.3%) and immunochemistry (+4.7%). In the UK, the only large market to experience overall growth, double-digit increase was seen in immunochemistry and hematology grew by 7.6%. These increases were offset by decreases in blood glucose testing and clinical chemistry overall. Despite the increasing number of Type II diabetic patients, significant reductions in expenditure have been noted, not only in the UK but also, in France and Germany.

European IVD Market Revenues (million €)



As in previous years, the continuing economic crises in Greece, Spain and Ireland saw decreases of 6.6%, 1.8% and 2.1% respectively. On the other hand, Portugal, which also suffered economic turmoil, showed a 1.8 increase in IVD expenditure.

In the newer EU member states, IVD expenditure averages 1.1% of total healthcare expenditure (THE) significant higher than the 0.7% seen in older member states (EU-15) but in absolute terms the new member states spend only €8 per capita compared to €23.1 in the EU-15. The growth in the newer states at 4.6% compared to a decline of 0.2% in the EU-15 states.

OVERVIEW

2014 Market Statistics

Countries	Population Thousands	GDP Mio €	GDP / capita €	THE Mio €	THE / capita €	THE as % GDP %	IVD mkt.2014 Mio €	IVD mkt.2013* Mio €	IVD mkt. growth rate 13-14 %	IVD mkt. / THE %	IVD mkt. / capita €
	Source Eurostat 2013	Source WHO 2013					Source EDMA				
Germany	80.767	2.737.600	33.895	309.272	3.829	11,3%	2.189	2.190	-0,1%	0,7%	27,1
France	65.835	2.059.852	31.288	240.214	3.649	11,6%	1.785	1.786	-0,1%	0,7%	27,1
UK	64.351	1.919.265	29.825	174.993	2.719	9,1%	812	796	2,0%	0,5%	12,6
Italy	60.782	1.560.024	25.666	141.820	2.333	9,0%	1.656	1.667	-0,7%	1,2%	27,2
Spain	46.512	1.022.988	21.994	90.834	1.953	8,9%	972	990	-1,8%	1,1%	20,9
Netherlands	16.829	602.658	35.811	77.654	4.614	12,9%	297	309	-3,9%	0,4%	17,6
Greece	10.903	182.054	16.698	17.881	1.640	9,8%	198	212	-6,6%	1,1%	18,2
Portugal	10.427	165.690	15.890	16.087	1.543	9,7%	221	217	1,8%	1,4%	21,2
Belgium	11.203	382.692	34.160	42.808	3.821	11,1%	362	356	1,7%	0,8%	32,3
Sweden	9.644	423.446	43.908	41.118	4.264	9,7%	191	185	3,2%	0,5%	19,8
Austria	8.506	313.067	36.805	34.544	4.061	11,3%	254	249	2,0%	0,7%	29,9
Denmark	5.617	248.815	44.297	26.432	4.706	10,6%	145	144	0,3%	0,5%	25,7
Finland	5.451	193.443	35.488	18.182	3.336	9,4%	107	105	1,9%	0,6%	19,6
Ireland	4.605	164.050	35.624	14.636	3.178	8,9%	93	95	-2,1%	0,6%	20,2
Luxembourg	549	45.478	81.749	3.228	5.880	7,1%	-	-	-	-	-
EU-15	401.981	12.021.122	29.905	1.249.704	3.109	10,4%	9.282	9.301	-0,2%	0,7%	23,1
Poland	38.017	393.724	10.357	26.234	690	6,6%	305	285	7,0%	1,2%	8,0
Romania	19.947	140.551	7.046	7.504	376	5,3%	100	93	7,5%	1,3%	5,0
Czech Rep	10.512	151.467	14.409	10.972	1.044	7,2%	150	143	4,9%	1,4%	14,3
Hungary	9.877	98.865	10.010	7.959	806	8,5%	62	61	1,6%	0,8%	6,3
Bulgaria	7.245	39.823	5.497	3.037	419	7,6%	30	32	-6,3%	1,0%	4,1
Slovakia	5.415	72.134	13.321	5.925	1.094	8,2%	45	44	2,3%	0,8%	8,3
Lithuania	2.943	34.521	11.730	2.153	732	6,2%	26	27	-3,7%	1,2%	8,8
Latvia	2.001	23.226	11.607	1.328	664	5,7%	24	23	4,3%	1,8%	12,0
Slovenia	2.061	37.246	18.072	3.231	1.568	8,8%	42	40	5,0%	1,2%	20,4
Estonia	1.315	18.613	14.154	1.065	810	5,7%	13	14	-4,3%	1,3%	10,2
Cyprus	858	16.504	19.235	1.227	1.430	7,4%	2	2	0,0%	0,2%	2,3
Malta	425	7.263	17.089	634	1.492	8,7%	2	2	0,0%	0,3%	4,7
New MS	100.616	1.033.937	10.276	71.269	708	6,9%	801	769	4,6%	1,1%	8,0
EU-27 (EU-15 + new MS)	502.597	13.055.060	25.975	1.320.973	2.628	10,3%	10.083	10.025	0,6%	0,8%	20,1
Switzerland	8.139	497.582	61.136	57.054	7.010	11,4%	370	345	7,2%	0,6%	45,5
Norway	5.107	357.153	69.934	34.190	6.695	9,5%	171	168	1,8%	0,5%	33,5
Iceland	325	11.075	34.077	1.003	3.086	9,0%	11	11	0,0%	1,1%	33,8
EFTA	13.571	865.810	63.799	92.247	6.797	4,2%	552	524	5,3%	0,6%	40,7
TOTAL (EU-27 + EFTA)	516.168	13.920.870	26.970	1.413.220	2.738	10,1%	10.635	10.549	0,8%	0,8%	20,6
Turkey	76.667	541.866	7.068	30.291	395	5,6%	394	370	6,5%	1,3%	5,1
TOTAL (EU-27 + EFTA + Turkey)	592.835	14.462.736	24.396	1.443.511	2434,929	10,0%	11.029	10.919	1,0%	0,8%	18,6

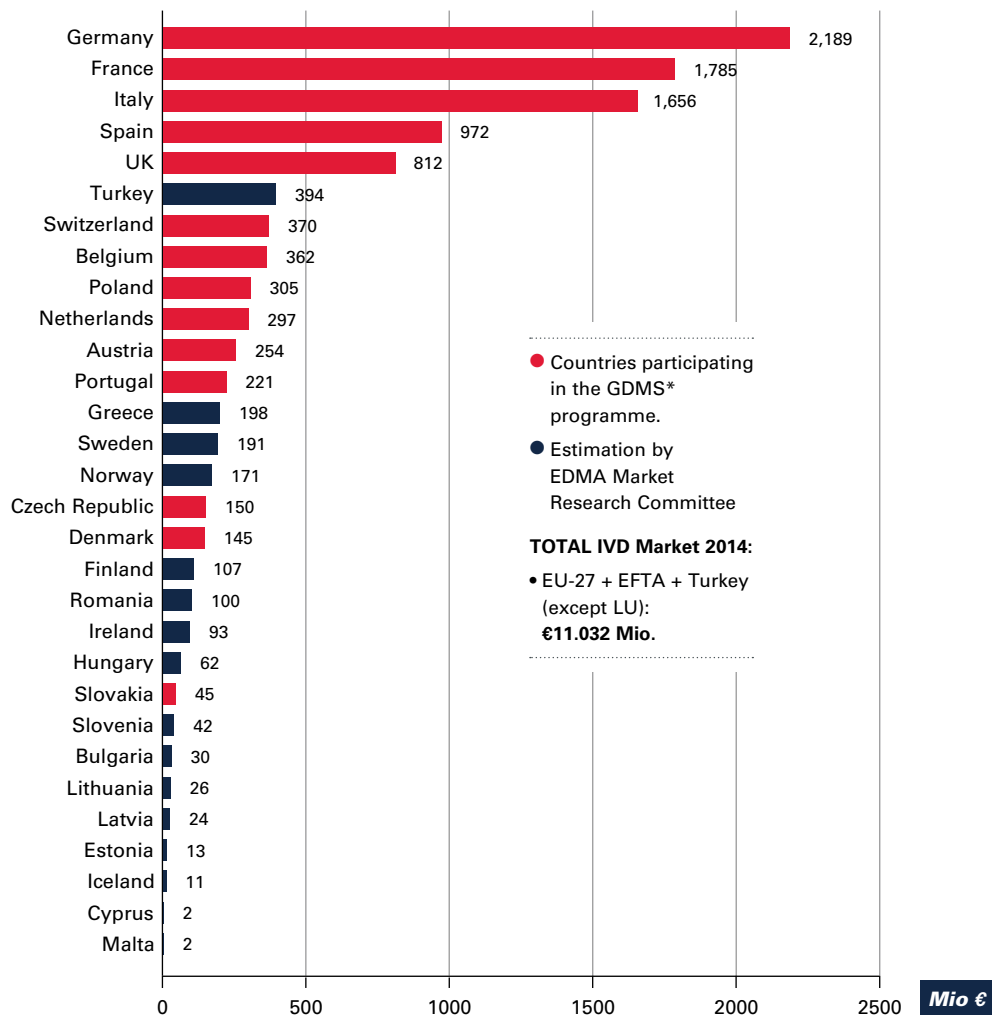
• The data regarding population, GDP and healthcare expenditure are from the World Health Organisation (WHO).

2014 EUROPEAN IVD MARKET

Although there are variations in healthcare systems, reimbursement policies, etc. from country to country, healthcare cost containment is a constant across the various countries in this report. Besides budget restrictions, greater centralization both in the public and private laboratory sectors has increased the power of purchasing organizations.

While Days Sales Outstanding (DSO) showed some improvement during 2013, the situation overall in 2014 remains unsatisfactory.

European IVD Market 2014 (million €)

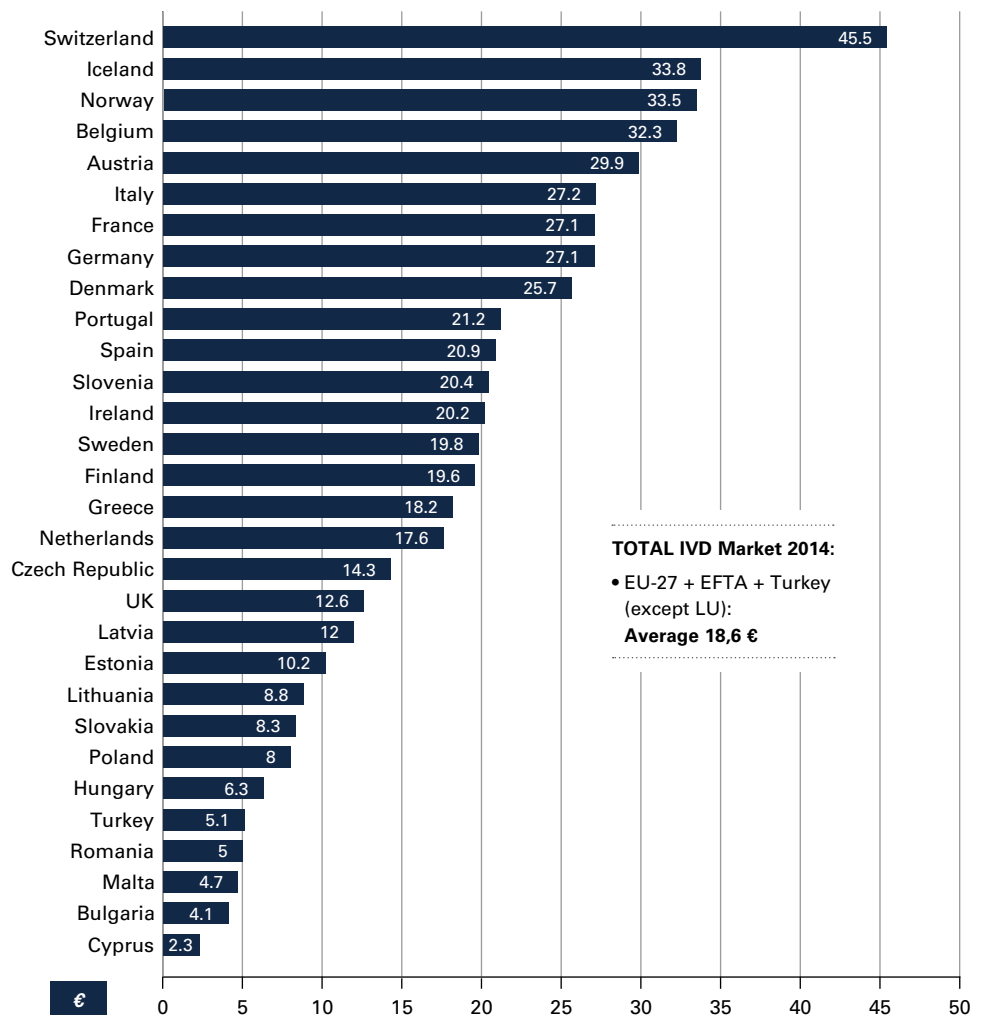


*GDMS = Global Diagnostic Market Statistics (formerly EDMS)

COUNTRY-SPECIFIC DATA

The differences in total healthcare expenditure, both in relative terms to GDP and absolute amounts, demonstrate the wide variation in access to healthcare across the thirty-one countries in this report. Relative to GDP, the Netherlands is the leading country at 12.9% while Switzerland, the Netherlands and the Scandinavian countries are the top five countries in absolute terms. The per capita expenditure also shows a wide variation from a low of €2.3 in Cyprus to €45.5 in Switzerland, which again is the leading country in per capita expenditure on IVD.

IVD Per Capita (€)



GERMANY DATA

Germany

"In 2014 the German IVD-Market showed a slight decrease of 0.1%. This means market stagnation for the second year in a row. As in previous years, changes in market size differ according to the separate market segments, but less dramatically than 2013. Laboratory diagnostics (reagents and instruments) grew by 0.7%. In contrast, the rapid test market decreased by 1.3%.

Glucose self-testing, which dominates the rapid test market, suffered a sales decrease of 3.2% in 2014. The decline was less significant for generic providers. The legal framework continued to be restrictive. Medical doctors are obliged to prescribe generic, low-price test strips for insulin-dependent patients and are under pressure to keep within budgets for glucose test strips.

The floating quota percentage arrangement for laboratory service fees (physicians in private practice) causes price pressure effects on the lab market in general. On the other hand, some positive results were observed. The market for microbiology reagents grew by a respectable 5.3%, while immunochemistry grew by 4.3%"

- VDGH, German IVD industry association



FRANCE DATA

France

"In 2014, for the third consecutive year, the in vitro diagnostics industry in France has declined. Sales to clinical laboratories, which represent 80% of the market, have once again declined by 0.4% compared to 2013. This decrease follows decreases of 0.3% in each of 2012 and 2013. The IVD market registered a €30 decrease since 2011. Unfortunately, this trend will not change in 2015, as indicated by our trend analysis at the time of publication. Mirroring the laboratory diagnostics sector, IVD sales in 2014 for the self-monitoring of blood glucose, remain the sales for 2009, despite the very high increase in the prevalence of diabetes and the corresponding volume of tests used."

- SIDIV, French IVD industry association



THE: Total Healthcare Expenditure
GDP: Gross Domestic Product



UNITED KINGDOM DATA



United Kingdom

"In contrast to 2013- the first year where the overall reported UK market size decreased - 2014 showed an increase in the UK IVD market of 2%. Clinical chemistry declined by £17 million (-€22 million) and this was due to a fall in the Rapid test and POC testing of £20 million (-€25.5 million), predominantly blood glucose testing. This trend may reflect the market conditions (as attempts were made to control expenditure by restricting testing, particularly those with type II diabetes), or it may also reveal an increase in the market share by non-participant companies, which is not estimated here.

In other market sectors growth has been moderate, apart from the cases of Immunochemistry (+7.6%) and Haematology which grew this time by a significant 11.3%. However, the reporting of haematology revenues can be effected by some double counting and the overall revenues may result in exaggeration."

- BIVDA, British IVD industry association



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ITALY DATA

Italy

“As in the previous year, 2014 was influenced negatively by changes in public financing. While the budget for the National Health Service (NHS) expenditure increased to €109.9 Billion (+2% vs. 2013), this increase is mainly due to the decision not to introduce a co-payment for patients that would have amounted to about €2 Billion.

Nevertheless, the various measures, that the government has introduced to respond to the situation in the NHS, have affected both the medical devices sector and IVD. As in the previous year, the 5% reduction in the value of outstanding contracts was confirmed during 2014. The application of this reduction was also extended to contracts that were in the process of being adjudicated. Based on a strictly literal interpretation of the regulations, the public administrations were authorized to make such reductions, but not obliged, in order to achieve their assigned budgetary objectives. During 2014, a ceiling of 4.4% of the national funding of the NHS was applied to the expenditure for medical devices. Above this ceiling, the Regions are responsible for expenditure. Although this provision relates specifically to medical devices, it also impacts the expenditure on IVD. As the database on NHS expenditure in medical devices is not capable of providing correct data at a national level, the Regions have reacted by asking hospitals and public laboratories to reduce budgets and expenditure on medical devices (and IVD).

The reorganization of networks aimed to concentrate on fewer labs, the establishment of territorial hubs and centralized bids, have had the impact of reducing the number of clients and revenues.

While 2014 registered a slight reduction in days sales outstanding (DSO), creditors still face about a 6 month delay based on the national average.

For all these reasons, 2014 IVD market (€1.656 Billion) showed a decline of -0.7% compared to 2013.”

- ASSOBIOMEDICA, Italian IVD industry association



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SPAIN DATA

Spain

"As the Spanish regions have to reach the deficit goal for 2014, strong budgetary restrictions remain in place. As a result, the IVD market stagnated with cost being the main driver in the purchasing process.

To achieve economies of scale, laboratory consolidation is also progressing. During the year, many mergers were seen, and with many medium and small labs, both public and private, disappearing. In this context, it remains very difficult to introduce new tests or to promote innovation.

Public tenders are getting bigger and taking longer to decide. Tenders for core lab are restricted to the big IVD players only.

The late payment situation improved a little but it is still far from the European directive."

- FENIN, Spanish IVD industry association



GREECE DATA

Greece

"After 6 years of continuous recession (from 2008 to 2013), reaching 27.4% in aggregate, Greek GDP was estimated to have grown by 0.6% in 2014. Initial projections showed a GDP growth of more than 2% in 2015. However, the slow pace of negotiations between the Greek government and its lenders has led to an extensive tightening of funds internally in the country, and a downward revision of this projection to close to zero. The Greek IVD market declined further by 6.6% in 2014, at € 198 million.

At the Public sector, accounting for about 70% of the total IVD market, the hospital operating expenses have been reduced by 50% in the last five years, while the relevant closed budget for 2015 is 14% lower compared to 2014 expenditure. At the same time, the public health expenditure has shrunk by 53% being well below 6% of, our dramatically reduced, GDP. (This continues in 2015, when state budget for the healthcare sector is 10.9% lower than the 2014 expenses). The state funding for the hospitals of the national healthcare system follows a downward trend: -31.5% from 2013 to 2015. The state funding for EOPYY, the main national insurance provider, follows a similar trend: -52.5% from 2013 to 2015.

Public procurement is dictated by the Observatory of Prices of the MoH, which continuously pushes prices down, regardless of technical specifications, volumes or method.

The private sector – accounting for less than 35% of the national healthcare expenses – is also under a lot of pressure. Private healthcare providers have suffered great losses in the form of claw-backs and rebates towards the main insurance provider, EOPYY. As a consequence, some of them have been forced out of business while the survivors are attempting to pass these losses over to their suppliers.

Most of the IVD suppliers still suffer from the losses imposed to them in 2012 by the haircut of the Greek Government bonds that were given to them as payment for the public sector purchases of the period 2007-2009. These losses are still having an impact and left a lasting effect on the Greek IVD market.

DSO decreased from 450 days at the end of 2013 to 350 days at the end of 2014.

In the future, both, centralised and e-procurement, are expected to become of greater importance and the relevant legal framework has already been established."

- SEIV, Greek IVD industry association



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PORTUGAL DATA

Portugal

"During 2014, the Portuguese IVD market had an increase of 1.8%. The main reason was a price increase from April to October for the blood glucose strips, however, the remaining IVD market maintained stable."

During 2014, DSO increased from 571 days in 2013 to 619 days. The collection situation remains a critical issue.

In the private sector, we continue to observe consolidation, but at a slower pace than in the previous years."

- APIFARMA, Portuguese IVD industry association



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BELGIUM DATA

Belgium

"In 2014, the overall IVD market grew by 1.7%

The increase (1.4% in total reagent consisted of gains in Clinical Chemistry (+1.7 %), Immunochemistry (+3.1%) and Infectious Immunology (+1.0%)

These increases were offset by revenue reductions in: Haematology/Histology/Cytology of nearly 0.4%, Haematology reagents (-7% and Microbiology (culture of just over 2.6%).

Instruments, Consumables, Software experienced a growth of +7.2%.

Within the total national healthcare budget 2014, the IVD expenditures decreased by 1.7% compared to 2013. The decrease is explained by a decrease of 9.8 % (€40 million) in expenses relating to the standard medical fees per prescription.

Otherwise, the circumstances of the IVD market in 2014 did not change dramatically compared to 2013:

Reimbursement dossiers remained on hold.

There is no budget for innovation due to the postponement of the revision of the current nomenclature, and the impact of "silo" budgeting is that there is a lack of a holistic view on healthcare. Increasing power of purchasing departments and an increasing degree of purchasing centralization result in:

- *decreasing prices due to globalised procurement and tenders.*
- *Tenders shifting more responsibility to suppliers and away from hospitals.*

At the end of 2014, the new minister of health started discussions regarding the reorganization of hospital funding and the introduction of innovative technology.

Vlerick Business School in cooperation with all the stakeholders, including UNAMEC initiated the 'Oncology horizon scanning project'.

This project will provide the Belgian health regulatory and payment authorities, actors and influencers with recommendations on how to ensure an improvement in patient access to precision medicine i.e. targeted therapeutics and companion diagnostics in the near future (< 5 years) in the field of oncology. The project will be finalized in 2015."

- UNAMEC, Belgian IVD industry association



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HUNGARY DATA

Hungary

"The Hungarian market increased slightly in 2014 with a growth of 1.6%. Meanwhile, the private laboratory service market which relies on out-of-pocket payment by patients experienced an overall increase of 30%. The budget for the reimbursement of laboratory services has been frozen since 2002. During 2013, the laboratory reagents and instruments shares of the total IVD market remained the same as in 2013."

- HIVDA, Hungarian IVD industry association



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SLOVENIA DATA

Slovenia

"After almost 6% decline in 2013, as result of price erosion in practically all areas, but especially in Diabetes and Immunochemistry, the trend stopped in 2014. The biggest contributors to the positive development (+5 % growth) in 2014 are laboratory reagents (Immunochemistry with double digit growth)."

"While the market value is regaining it must be taken into consideration, that the growth depends mainly on the number of tests sold, but the very low numbers of instruments purchased by public institutions depress revenues."

- SIEDMA, Slovenian IVD industry association



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TURKEY DATA

Turkey

"In 2014, Turkey kept experiencing market erosion due to the increasing bargaining power, stemming from the consolidation of public hospitals under public hospital consortia, as well as full service tender concept. Single-digit growth is a consequence of cost-containment measures on the healthcare sector. This was also reflected in hospital budgets and reimbursement tariffs of the social security institution, the main payer for public hospitals. Government financial support for university hospitals weakened which resulted in prolonged payment terms.

On the other hand, private healthcare service utilization has increased and Turkey's Ministry of Health initiated a PPP program that will cover approximately 36-40 health campuses with a total bed capacity of 30.000. The IVD market, when expressed in Euros has substantially decreased, as the Turkish Lira (TL) lost around 20% of its value against the Euro compared to the previous year. As a result of long term TL-based contracts signed by companies and public hospitals, profitability and thus sustainability of the system, remains a serious problem."

- Arted, Turkish IVD industry association



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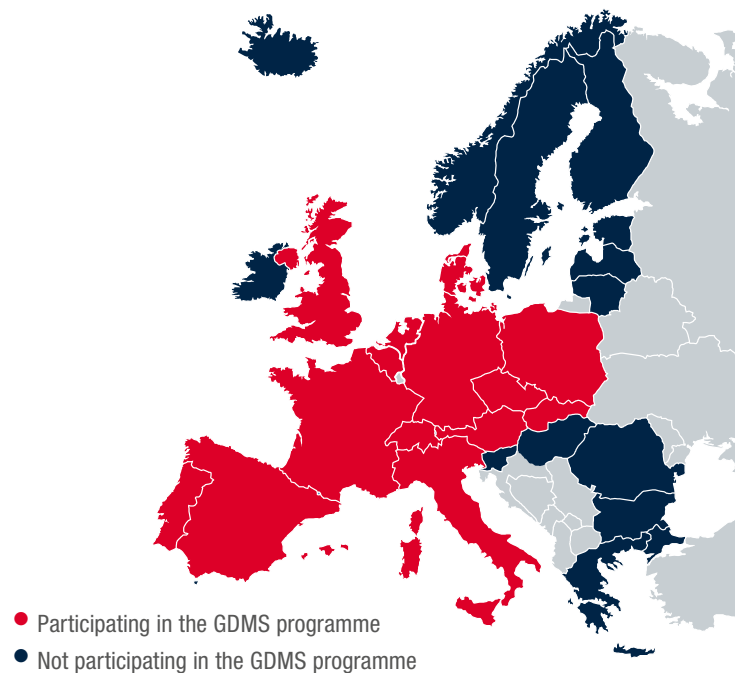
DATA GATHERING



The results presented above are based on individual estimates made for 26 EU countries and the EFTA countries:

- 14 countries participating in the Global Diagnostic Market Statistics (GDMS, former 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 GDMS programme: *Bulgaria, Cyprus, Estonia, Finland, Greece, Hungary, Iceland, Ireland, Latvia, Lithuania, Malta, Norway, Romania, Slovenia, and Sweden.*

14 countries participating in the Global Diagnostic Market Statistics (GDMS) programme



The EDMA figures per country are compiled from the Global Diagnostic Market Statistics (GDMS) 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 GDMS, 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 GDMS 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

European Diagnostic Manufacturers Association (EDMA) is an international, non-profit organisation representing the interests of the medical in vitro diagnostics (IVD) industry in Europe. Its mission is to promote the value of IVDs in delivering sustainable and effective public health systems, and provide technical, regulatory and market research information to its members. The European IVD industry is a market worth around €11 billion. 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. EDMA is a member of MedTech Europe, an alliance of European medical technology industry associations. For more information, visit www.edma-ivd.eu.

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