European IVD Market Statistics Report



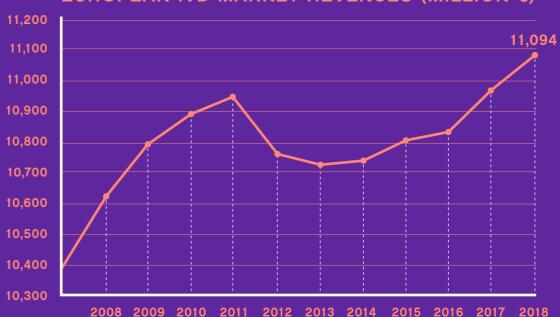
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MedTech Europe is pleased to publish the market estimates of the in vitro diagnostic (IVD) industry in Europe. The MedTech Europe figures include market size and dynamics information, based on 2018 and 2017 data. Macroeconomic and healthcare data are also included for all 28 EU-member states plus the European Free Trade Association members (EFTA) –Switzerland, Norway and Iceland, as well as for Turkey.

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 healthier populations, reduced costs and economic growth in the long run.

Three out of the five largest European IVD markets – France, Spain and the UK are showing slight to moderate growth in 2018 and overall revenues across EU-28 plus EFTA reached €11,094 million, an increase of +1.2%. If changes in the value of non-Euro currencies, especially the depreciation of the pound sterling, are considered, the overall change in the Euro value of the European IVD market from 2017 to 2018 is +1.3%.

EUROPEAN IVD MARKET REVENUES (MILLION €)



The IVD revenues in Germany decreased overall (-1.6%). Further market decrease was seen in the rapid test market (-4.8%) and blood glucose test strips (-6%). In Italy the IVD market stagnated (-0.2%), with decreased revenues in both clinical glucose tests (-8%), and clinical chemistry (-4.9%). From the largest five markets, the UK is experiencing the highest increase of +3.3%, largely due to increase in the glucose test strip market, but also reflecting depreciation of the pound sterling. In Spain, the IVD market increased by +1.5%. After decreasing for three consecutive years (2012 – 2014), and stagnation in 2015 and 2016, the French IVD market registered a second year of growth of +0.8%. The changes in revenues do not necessarily reflect changes in test volumes, and there is evidence in many countries that volumes have increased significantly without increased revenues. For the third time since 2008, the Greek IVD market marked an increase of + 3.7% in 2018. On the other hand, Denmark reported a -5.3% decrease in IVD expenditure.

In the newer EU member states, IVD expenditure averaged 1.3% of total healthcare expenditure (THE), significantly higher than the 0.63% seen in older member states (EU-15), but in absolute terms, the new member states spend only €11 per capita compared to €22.8 in the EU-15. Growth in the newer states are at +5.8 compared to 0.8% in EU-15 states.

IVD Market Statistics

Countries	Population	GDP	GDP / capita	THE	THE / capita	THE as % GDP	IVD mkt. 2018	IVD mkt. 2017	IVD mkt. growth rate 18-17	IVD mkt. / THE	IVD mkt. / capita
	1000	Mio €	€	Mio €	€	%	Mio €	Mio €	%	%	€
	Eurostat 2018			OECD/WHO 2018			Source MedTech Europe				
Germany	82.792	3.344.370	40.395	380.225	4.593	11,4%	2.156	2.191	-1,6%	0,6%	26,0
France ¹	66.926	2.353.090	35.159	263.014	3.930	11,2%	1.614	1.601	0,8%	0,6%	24,1
UK ²	66.274	2.419.186	36.503	233.837	3.528	9,7%	974	942	3,3%	0,4%	14,7
Italy	60.484	1.765.421	29.188	154.836	2.560	8,8%	1.610	1.613	-0,2%	1,0%	26,6
Spain	46.658	1.202.193	25.766	107.050	2.294	8,9%	999	985	1,5%	0,9%	21,4
Netherlands	17.181	774.039	45.052	76.884	4.475	9,9%	286	269	6,5%	0,4%	16,6
Greece	10.741	184.714	17.197	14.492	1.349	7,8%	198	191	3,7%	1,4%	18,4
Portugal	10.291	203.896	19.813	18.345	1.783	9,0%	229	224	1,7%	1,2%	22,2
Belgium	11.399	459.820	40.340	46.727	4.099	10,2%	386	371	4,0%	0,8%	33,9
Sweden	10.120	471.196	46.560	51.566	5.095	10,9%	184	184	0,2%	0,4%	18,2
Austria	8.822	385.712	43.720	39.883	4.521	10,3%	262	258	1,5%	0,7%	29,7
Denmark	5.781	301.341	52.124	31.163	5.390	10,3%	145	153	-5,3%	0,5%	25,1
Finland	5.513	234.453	42,526	21.232	3.851	9,1%	117	110	6,6%	0,6%	21,3
Ireland	4.830	324.038	67.083	22.382	4.634	6,9%	117	108	8,3%	0,5%	24,2
Luxembourg	602	60.053	99.755	3.184	5.288	5,3%	19	19	0,0%	0,6%	31,6
EU-15	408.416	14.483.522	35.463	1.464.819	3.587	10,1%	9.296	9.219	0,8%	0,6%	22,8
Poland	37.977	496.361	13.070	31.225	822	6,3%	399	391	2,1%	1,3%	10,5
Romania	19.531	202.884	10.388	8.221	421	4,1%	185	165	12,1%	2,3%	9,5
Czechia	10.610	207.772	19.583	15.416	1.453	7,4%	170	168	1,1%	1,1%	16,0
Hungary	9.778	133.782	13.681	8.702	890	6,5%	81	73	11,1%	0,9%	8,3
Bulgaria	7.050	56.087	7.956	3.961	562	7,1%	32	30	6,4%	0,8%	4,6
Slovakia	5.443	89.721	16.483	6.069	1.115	6,8%	75	72	3,4%	1,2%	13,8
Croatia*	4.105	51.579	12.563	3.380	823	6,6%	65	61	6,3%	1,9%	15,7
Lithuania	2.809	45.264	16.115	3.070	1.093	6,8%	29	28	3,2%	0,9%	10,3
Latvia	1.934	29.151	15.070	1.732	895	5,9%	24	22	8,7%	1,4%	12,4
Slovenia	2.067	45.755	22.137	3.651	1.766	8,0%	52	50	4,2%	1,4%	25,2
Estonia	1.319	26.036	19.737	1.655	1.254	6,4%	21	19	11,7%	1,3%	15,9
Cyprus	864	21.138	24.458	1.253	1.450	5,9%	10	10	0,0%	0,8%	11,0
Malta	476	12.324	25.907	948	1.993	7,7%	5	5	0,0%	0,5%	10,5
New MS	103.964	1.417.854	13.638	89.283	859	6,3%	1.147	1.093	5,8%	1,3%	11,0
EU-28 (EU-15 + new MS)	512.379	15.901.376	31.034	1.554.102	3.033	9,8%	10.443	10.312	1,3%	0,7%	20,4
Switzerland	8.484	597.009	70.368	72.797	8.580	12,2%	462	462	0,2%	0,6%	54,5
Norway	5.296	367.894	69.471	37.514	7.084	10,2%	178	180	-1,3%	0,5%	33,6
Iceland	348	21.988	63.101	1.832	5.258	8,3%	11	11	0,0%	0,6%	31,6
EFTA	14.128	986.890	69.853	112.143	7.938	11,4%	651	653	-0,2%	0,6%	46,1
TOTAL (EU-28 + EFTA)	526.507	16.888.266	32.076	1.666.245	3.165	9,9%	11.095	10.965	1,2%	0,7%	21,1
Turkey ³	80.811	652.520	8.075	27.701	343	4,2%	645	487	32,5%	2,3%	7,99
TOTAL (EU-28 + EFTA + Turkey)	607.318	17.540.786	28.882	1.693.946	2.789	9,7%	11.739	11.452	2,6%	0,7%	19,3

¹⁾ France data includes only the Central Laboratory IVD Market.

The applied exchange rates are the 2018 annual average exchange rates published by The European Central Bank. Applying a single exchange rate to both 2017 and 2018 sales data eliminates possible market size and market growth fluctuations due to exchange variations. The impact of these fluctuations is shown in the table below.

During the collection of 2018 figures, the 2017 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 2017. The growth rate between 2018 and 2017 has been calculated using the re-estimated figures.

The data regarding population, GDP and healthcare expenditure are the latest available from Eurostat, the Organisation for Economic Co-operation and Development (OECD) and the World Health Organisation (WHO).

IVD Market Size in Mio Euro (using actual exchange rates)

Country	Currency	2018 average Exchange Rate	2017 average Exchange Rate	IVD mkt. 2018 Mio LC	IVD mkt. 2017 Mio LC	IVD mkt. 2018 Mio €	IVD mkt. 2017 Mio €	IVD mkt. growth rate 18-17
UK	GBP	1,1304	1,1413	861	833	974	951	2,3%
Sweden	SEK	0,09752	0,10381	1.891	1.772	184	196	-5,9%
Denmark	DKK	0,134171	0,134433	1.082	1.142	145	154	-5,5%
EU-15	EUR	N/A	N/A	N/A	N/A	9.296	9.240	0,6%
Poland	PLN	0,2347	0,2349	1.700	1.664	399	391	2,1%
Romania	RON	0,2151	0,2189	84.600	75.440	185	165	12,2%
Czech Rep	CZK	0,03899	0,038965	4.352	4.306	170	168	1,1%
Hungary	HUF	0,003137	0,003234	25.681	23.346	81	76	6,7%
Bulgaria	BGN	0,511305	0,511305	63	59	32	30	6,4%
Croatia	HRK	0,134	0,134	481	453	65	61	6,3%
New MS	EUR	N/A	N/A	N/A	N/A	1.147	1.096	4,7%
EU-28 (EU-15 + new MS)	EUR	N/A	N/A	N/A	N/A	10.443	10.336	1,0%
Turkey	TRY	0,1794	0,2434	2.650.275	2.000.887	475.459	487.016	-2,4%

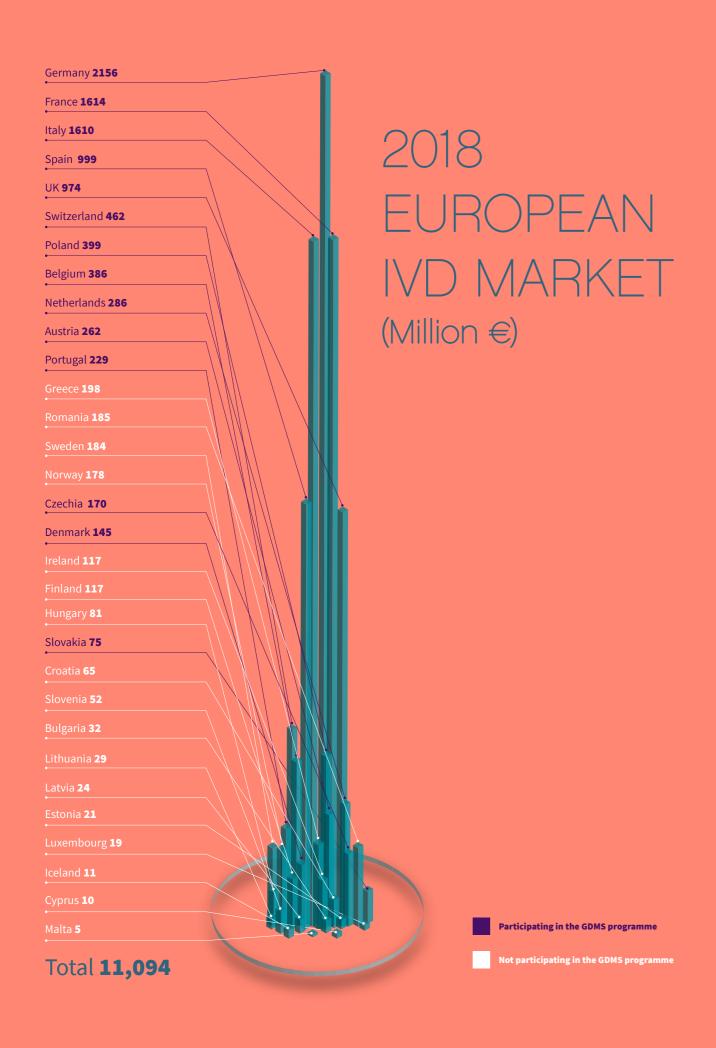
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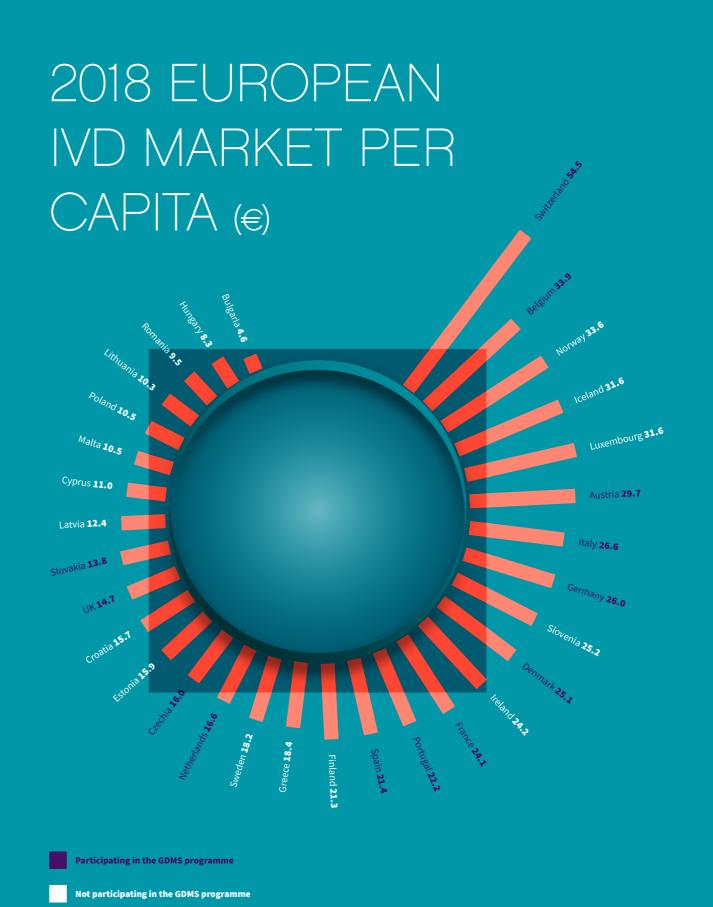
The differences in total healthcare expenditure, both in relative terms to GDP and absolute amounts, demonstrate the wide variation in access to healthcare across the thirty-two countries in this report. Relative to GDP, Switzerland is the leading country at 12.2%, followed by Germany, France and the Scandinavian countries. In absolute amounts, the healthcare expenditure per capita in Switzerland remains in first position, followed by Norway, Luxembourg, Denmark and Sweden.

The IVD per capita expenditure also shows a wide variation from a low of €4.6 in Bulgaria to €54.5 in Switzerland, which remains also the leading country.

Although there are variations in healthcare systems, reimbursement policies etc. from country to country, healthcare cost containment is constant across the various countries in this report. Besides budget restrictions, greater centralisation both in the public and private laboratory sectors has increased the power of purchasing organisations. The overall situation with days sales outstanding (DSO) in 2018 remains unsatisfactory.

²⁾ UK data reflects the consolidated sales of the participating companies in GDMS, plus the figures published by NHS England for glucose test strip sales adjusted to represent the whole of the UK.





Germany

-1.6% IVD MARKET 2156 M EUR

"In 2018, the German IVD market shows a sales decline of 1.6% to 2.156 billion euros. This continues the downward trend of the previous year (-2.2 %). The picture differed in the individual market segments. Sales for laboratory diagnostics (reagents and instruments) stagnated (-0.1 %). In the rapid test market (R + I), sales fell by 4.8 %. The laboratory market is suffering under the restrictive conditions for the remuneration of laboratory physicians. Almost all services are budgeted. In clinical chemistry, there is also considerable price pressure. Slight growth can still be seen in microbiology and infectious immunology. A 6 % decline in the market for blood glucose test strips dominates the entire rapid test market. However, this should be offset by significant growth in sensor-based glucose measurement (FGM, CGM). Sales for FGM and CGM cannot currently be recorded." - VDGH, German IVD industry association

Spain +1.5% IVD MARKET 999 M EUR

"The IVD market in Spain continues with small growth. Mature test markets are declining due to price reductions and new test incorporation is not enough to get a clear positive trend. Aggregated purchasing and consolidation of laboratories is a trend but there is not too much room for consolidation. Most of laboratories are already consolidated and looking for economy of scale and homogenization of the region's procedures and technologies. Customers are looking for new contracts based on risk sharing or value-based considerations but the implementation of these kinds of contracts is only testimonial. Costs increase for automation and digitalisation in the context of a price driven market, especially in core labs. Introduction of innovative technology or new tests remains slow due to a very heterogeneous market with 17 autonomous regions with different technology incorporation processes and purchase approaches. There is no central process to incorporate new technologies. Market needs a tailor-made case by case approach. Continuous monitoring of glucose is generally reimbursed in many regions subject to individual approval. Other glucose test strips suffer a commoditization approach. Disappointing evolution of point of care, lacking a clear model of reimbursement but it seems it could improve in the future as it gets more recognition."- FENIN, Spanish IVD industry association

taly -0.2% IVD MARKET 1610 M EUR

"In 2018, the Italian IVD market has slightly decreased by -0.2%. There are some reasons that help to explain such decrease. First, a co-payment system is still working and, even though some patient categories are excluded, other patients have to pay an amount up to € 70.00 (only in some regions) for tests. Second, the drop of the glucose test market is another factor to explain the overall decrease. In fact, this market went down (-8.0%), and this figure influenced the IVD market. Generally, some segments of the IVD market increased compared to the previous year (mainly one of the smallest as the "genetic test") while others decreased. It is important to stress that in 2019 many regions adopted a tighten cost containment strategies. On one hand the central government went on putting some limits to finance healthcare expenditure (and the ceiling limit of expenditure for devices is still 4.4% of the public healthcare expenditure). On the other hand, regions – that should have already received funds by pharmaceutical companies due to the pharma payback (excess expenditure on the pharmaceutical ceiling) did not receive such funds. "- Confindustria Dispositivi Medici, Italian IVD industry association

France +0.8% IVD MARKET 1614 M EUR

"The Central Laboratory IVD French market is estimated at 1.614 billion €, with a growth of +0.8% compared to 2017. The Central Laboratory IVD French market has been in stagnation since 2014 with continuous non-significant growth of less than 1%." - SIDIV, French IVD industry association

United Kingdom

+3.3% IVD MARKET 974 M EUR

"The referendum result of 2016 to leave the European Union resulted in the resignation of David Cameron as leader of the Conservative Party and therefore as Prime Minister, and the appointment of Theresa May. She took the country to the polls to try to establish a strong base from which to lead negotiations. The result was a worsening of her position resulting in the necessity of forming an alliance with the DUP, a party representing Northern Ireland constituents. Although Article 50 was triggered with the support of Parliament, the terms of the Withdrawal Agreement negotiated by Mrs. May's team were repeatedly rejected, and eventually a leadership challenge resulted in her removal and the election, by Conservative Party members, of Boris Johnson, who committed to 'deliver Brexit' without fail by October 31st, the revised deadline agreed with the EU after the March 29th date was passed without a conclusion to the process. This deadline has also passed, and a general election has now been called for 12th December. If the Conservative party attains a majority they will proceed with the withdrawal agreement immediately and the UK will leave fully by the end of 2020, regardless of whether trade agreements have been concluded. Preparations for a 'no deal' exit from the EU are claimed by the government to be well advanced, but this is disputed by many. Some suppliers of IVDs have made provision for increased stockholdings and alternative transport arrangements to try to prevent delays to supply of critical products. A great deal of uncertainty and anxiety clouds ongoing business activities and relationships at present. The state of the National Health Service remains critical while government is paralysed, and there are major concerns about overcoming staff shortages if movement of people between countries becomes more difficult. Already a large number of non-UK nationals working in the NHS have left, and this, combined with punitive taxation of doctors who work additional hours to cover shortfalls is creating severe problems. A recent report has shown that life expectancy and survival rates for some cancers has deteriorated in the last few years, and waiting times are increasing. The consolidation of Pathology Services is still being driven by NHS England as a way to derive greater productivity from the service, i.e. to cope with increasing demand but require less funding. Such consolidations generally involve grouping of hospital laboratories which are geographically close enough to increase economies of scale and maximise the usage of equipment and staff while not reducing the level of service. Capital is not always available to help implement these consolidations, but with creative finance schemes such as Managed Services Contracts and Cost per Reportable charging new equipment is being acquired. Cost savings have been demonstrated by some of these new laboratory groups in blood sciences services, but in other disciplines, e.g. Microbiology it is harder to find a real case study where this can be demonstrated. Seasonal flu contributed to the worst winter for a decade in 2017/18 in terms of pressures on emergency departments and ICUs, and the availability of rapid POC tests to help diagnose and manage patients in terms of isolation requirements and treatment was seized upon by a number of hospitals, resulting in rapid adoption of both specific POC tests for flu and multiple test systems (adopting a syndromic testing approach whereby infective agents are identified rather than screened negative or positive for a specific agent). The recognition of the value of IVDs as tools for patient and bed management is a positive step forward for the industry, as test costs are easily offset by savings in overall health care costs, even to the point of enabling services to be kept open." - BIVDA, British IVD industry association

Poland

+2.1% IVD MARKET 399 M EUR

"Compared to the previous year, the Polish market observed an increase of +2.1%." - MedTech Polska, Polish IVD industry association

Portugal

+1.7% IVD MARKET 229 M EUR

"The IVD market in Portugal has been quite stable, showing a non-significant difference in 2018. Short term tendering and contracts adding to political measures to contain costs in healthcare, specifically with medical devices, leads to high pressure on prices. Positive market development from organic growth (higher life expectancy and increase in the elderly population) is being compensated by a market value decrease with cost control measures and high competition. Several policies and trends have been shaping the healthcare panorama in terms of funding, provision and access. Public funding is leaning towards more cost-effective and integrated care, with an increasing role for insurance companies and significant changes in the health subsystems (e.g ADSE). The growth of private funding has stabilized, but health insurance continues to gain relevance with ~25% population insured and a growing number of private hospitals. Intensive consolidation has happened in the private lab sector, with large international chains acquiring many small labs. Portugal has been witnessing increasing patient empowerment and education, with a shift of disease management from reactive to preventive. Public policies are focused at improving screening and integrating hospitals and primary care, while centralising purchases for the NHS. Discussions are arising on new models of funding healthcare, like value-based purchasing and payments over results in health. Uncertainties on the payments from the public institutions continue. The diagnostics companies close 2018 with DSO (days of sales outstanding) of 368 days." - APIFARMA, Portuguese IVD industry association

Greece

+3.7% IVD MARKET 198 M EUR

"Following a multi-year economic crisis, the Greek economy is showing signs of recovery, with a 3% GDP increase from 2017 to 2018, in terms of Euro. It must also be noted that as of September 1st, 2019, capital controls are no longer in effect. The Greek IVD market grew in 2018, for third consecutive time after 2008 by 3.7%, reaching a size of € 198M. 65% of the Greek IVD market comes from the public sector, while the remaining 35% comes from the private sector. The total public health spending in 2018 remained stable from 2017 at 5.1% of GDP. This number lags significantly behind the European average of 7.2%. Public procurement, based on tenders and negotiations, is dictated by the Observatory of Prices of the Ministry of Health, which continuously pushes prices down, regardless of technical specifications, volumes or method. Under the current law, the criterion of lowest price is of higher importance than the criteria of quality and most advantageous economic offer in the majority of public tenders. In recent years, there have been several efforts to create the prerequisites for centralised procurement in the IVD sector, but without successful results so far. The private sector – accounting for approximately 35% of the total IVD market in Greece – is also under a lot of pressure and has contracted by more than 30% since 2009. Private healthcare providers (Private Labs) have been constantly suffering great losses annually, since 2013, in the form of clawbacks and rebates (reaching cumulatively even 40% in several cases) towards the main insurance provider, EOPYY, hence, some of them have been pushed out of business while the survivors are attempting to pass these losses over to their suppliers. DSO remained on average stable at 200 days during 2018; private sector ones increased, while public sector ones decreased." - SEIV, Greek IVD industry association

Slovenia +4.2% IVD MARKET 52 M EUR

"The IVD market has grown by +4.2% in 2018. The moderate growth momentum continued and had increased by +1 % point versus last year. The growth was mainly due to the Laboratory market, +9.2%, with an outstanding contribution by Chemistry/ Immunochemistry Instruments (+ 31.8%; most likely due to completion of some delayed tenders in 2018), and Infectious Immunology reagents + 25.5%. Overall Immunochemistry reagents kept the positive growth +3%, while a decline was recognized in Clinical Chemistry reagents (- 0.8%) and more significantly in Haematology Reagents (- 15.3%). Diabetes market and POC markets stayed on the same level, with slight decreases; Diabetes (- 0.9%) and POC (- 1.8%). Significant price pressure on the IVD industry and distributors continued, and the most prominent public institution has frequently requested price reductions. The same trend was seen in public tenders." - SIEDMA. Slovenian IVD industry association

Turkey

-2.4% IVD MARKET 645 M EUR

"End-user market value growth in local currency has reached double digits (+30%) not only because of the upsurge in number of tests (10%) but also due to the depreciation of the Turkish Lira (50%) and high inflation (20%), which the suppliers and distributors could only partially reflect in prices since tender durations are 1-3 years and both depreciation and inflation accelerated in Q3 & Q4 (more reflection of cost increases to prices are to be expected in 2019 & 2020). Payment performance of state hospitals worsened in 2018 both because SUT reimbursement points (partly determining the income of hospitals) remained the same and the fact that overall cost pressure on hospitals continued to surge with high level of inflation. On the positive side, university hospitals' chronically accrued debts were paid to companies by the Ministry of Finance, albeit with discounts determined according to criteria based on age of debts (terms not accepted by all companies). The Budget deficit/GDP ratio increased to 2% by the end of 2018 due to increasing spending of public institutions; the upward trend is expected to continue within 2019, which might worsen the DSO's of companies. The opening of city hospitals financed by PPP models have continued. Five hospitals have been launched in 2018, increasing the total number of PPP hospitals to nine. Current estimation for the completed number of hospitals in 2023 stands at 18, which is short of originally planned 30, due to funding issues. As a long-term initiative, The Department of Medical Diagnosis Services initiated two projects on rational medical screening and laboratory usage to maintain cost-effective/ sustainable test requests, which is expected to lead to volume reductions at laboratory and screening services from 2019 onwards." - ARTED, Turkish IVD industry association

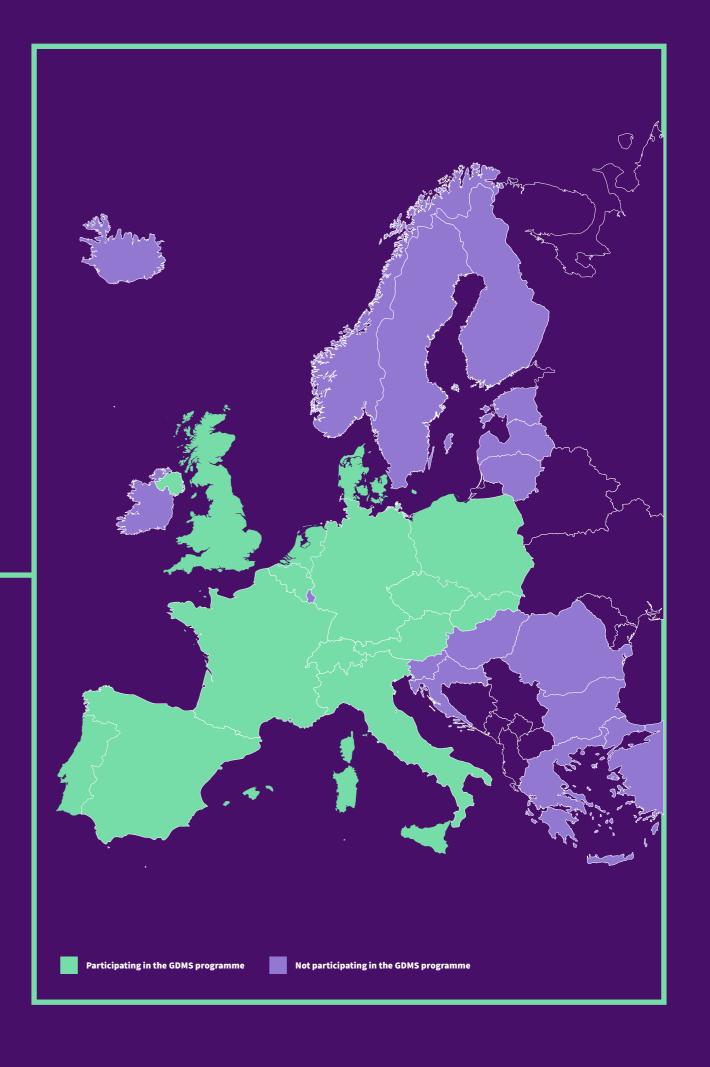
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The results presented above are based on individual 2018 estimates made for 28 EU countries, the EFTA countries and Turkey:

- 14 countries participating in the Global Diagnostic Market Statistics (GDMS, former EDMS) programme: Austria, Belgium, Czechia, Denmark, France, Germany, Italy, the Netherlands, Poland, Portugal, Slovakia, Spain, Switzerland, and the UK.
- The National Association Members of MedTech Europe and the MedTech Europe's Market Research Committee have estimated the IVD market in 18 other countries not participating in the GDMS programme: Bulgaria, Croatia, Cyprus, Estonia, Finland, Greece, Hungary, Iceland, Ireland, Latvia, Lithuania, Luxembourg, Malta, Norway, Romania, Slovenia, Sweden and Turkey.

The figures per country are compiled from the Global Diagnostic Market Statistics (GDMS) programme, through which companies report invoiced sales of reagents, instruments and consumables, as based on the Global IVD Classification. This is done in association with the MedTech Europe's Market Research Committee and the National Association Members.

More than 85% of the market is covered in major countries by GDMS, ensuring the reliability and objectiveness of the information provided by MedTech Europe and its members. MedTech Europe 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.



About In Vitro Diagnostics

In vitro diagnostics 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 its state of health. They are used for diagnosis, prognosis, risk stratification, 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 MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions. MedTech Europe's mission is to make innovative medical technology available to more people, while helping healthcare systems move towards a sustainable path. MedTech Europe encourages policies that help the medical technology industry meet Europe's growing healthcare needs and expectations. It also promotes medical technology's value for Europe focusing on innovation and stakeholder relations, using economic research and data, communications, industry events and training sessions.

The European in vitro diagnostic industry is a market worth around €11 billion. Driven by research and development, 95% of the industry is comprised of small and medium sized enterprises and approximately 1 billion euros per year is reinvested in R&D. Developed by MedTech Europe, the Global Diagnostic Market Statistics (GDMS) and Management Information System (MIS) programmes provide a comprehensive overview of the latest market trends based on the Global IVD Product Classification (GIVD). For more information, visit http://www.medtecheurope.org.

For more information

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