

# European IVD Market Statistics

REPORT 2017

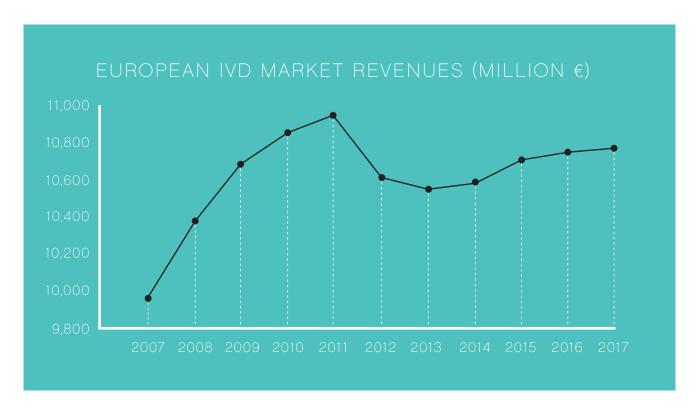
Real data, Trusted service, Informed decisions



MedTech Europe is pleased to publish the market estimates of the In Vitro Diagnostic (IVD) industry in Europe, for the year 2017. The MedTech Europe figures include macroeconomic and healthcare data for all 28-member states plus the European Free Trade Association members – Switzerland, Norway and Iceland.

In vitro diagnostics 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.

Four out of the five largest European IVD markets (Germany being the exception), are showing slight growth in 2017 and overall revenues across EU-28 plus EFTA reached €10,768 million, only increasing +0.1% However, this remains below the revenues recorded in 2011 (€10,943), and, if changes in the value of non-Euro currencies, especially the depreciation of sterling, are taken into account the overall change in the Euro value of the European IVD market from 2016 to 2017 is negligible (-0.4%).



While the IVD revenues in Germany decreased overall (-2.2%), market growth was seen in both microbiology (+4.5%), and infectious immunology reagents (+2%). From the largest five markets, the UK has experienced the highest increase of +2%, largely due to increase in the glucose test strip market, but also reflecting depreciation of the pound sterling. In Italy the IVD market increased slightly (+0,4%), with decreased revenues in both clinical glucose tests, (-2.1%) and infectious immunology, (-1.7%). After decreasing for three consecutive years (2012 – 2014), and stagnation in 2015, the French IVD market registered a growth of +1.1%. In Spain, the IVD market remained flat with growth of +0.2%. 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 second time since 2008, the Greek IVD market marked an increase, + 1.1% in 2017. On the contrary, Ireland reported a -6.5% decrease in IVD expenditure.

In the newer EU member states, IVD expenditure averaged 1.25% of total healthcare expenditure (THE), significantly higher than the 0.64% seen in older member states (EU-15), but in absolute terms the new member states spend only €10.2 per capita compared to €22.2 in the EU-15. Growth in the newer states at +3.3% compares to -0.2% in the EU-15 states.

#### **IVD Market Statistics**

Countries	Population	GDP	GDP / capita	THE	THE / capita	THE as % GDP	IVD mkt. 2017	IVD mkt. 2016*	IVD mkt. growth rate 17-16	IVD mkt. / THE	IVD mkt. / capita
	1000	Mio €	€	Mio €	€	%	Mio€	Mio €	%	%	€
	Eurostat 2017			OECD 2017			Source MedTech Europe				
Germany	82.521	3.277.340	39.715	367.831	4.457	11,2%	2.186	2.234	-2,1%	0,6%	26,5
France <sup>1</sup>	66.989	2.291.705	34.210	262.105	3.913	11,4%	1.440	1.425	1,1%	0,5%	21,5
UK <sup>2</sup>	65.808	2.332.087	35.438	222.745	3.385	9,6%	936	918	2,0%	0,4%	14,2
Italy	60.589	1.724.955	28.470	152.817	2.522	8,9%	1.613	1.606	0,4%	1,1%	26,6
Spain	46.527	1.166.319	25.068	102.881	2.211	8,8%	987	985	0,2%	1,0%	21,2
Netherlands	17.081	737.048	43.150	74.362	4.353	10,1%	269	273	-1,5%	0,4%	15,7
Greece	10.768	180.218	16.736	14.869	1.381	8,3%	191	189	1,1%	1,3%	17,7
Portugal	10.309	194.614	18.878	17.345	1.682	8,9%	224	227	-1,3%	1,3%	21,7
Belgium	11.352	439.052	38.676	43.809	3.859	10,0%	371	373	-0,6%	0,8%	32,7
Sweden	9.995	475.231	47.547	50.442	5.047	10,6%	184	180	2,3%	0,4%	18,4
Austria	8.773	369.899	42.163	38.107	4.344	10,3%	258	258	0,0%	0,7%	29,4
Denmark	5.749	288.981	50.266	29.438	5.121	10,2%	153	150	2,2%	0,5%	26,7
Finland	5.503	223.843	40.677	20.623	3.748	9,2%	110	115	-4,5%	0,5%	20,0
Ireland	4.784	294.110	61.478	21.012	4.392	7,1%	106	114	-6,5%	0,5%	22,2
Luxembourg	591	55.299	93.569	3.367	5.697	6,1%	19	19	0,0%	0,6%	32,1
EU-15	407.339	14.050.701	34.494	1.421.753	3.490	10,1%	9.048	9.066	-0,2%	0,6%	22,2
Poland	37.973	467.167	12.303	31.209	822	6,7%	372	345	7,6%	1,2%	9,8
Romania*	19.644	187.940	9.567	7.925	403	4,2%	164	164	0,0%	2,1%	8,3
Czech Rep	10.578	191.643	18.117	13.980	1.322	7,3%	168	166	1,0%	1,2%	15,8
Hungary	9.798	124.050	12.661	8.805	899	7,1%	74	72	3,5%	0,8%	7,6
Bulgaria*	7.102	51.663	7.274	3.298	464	6,4%	30	29	5,2%	0,9%	4,3
Slovakia	5.435	84.851	15.612	6.000	1.104	7,1%	72	76	-5,2%	1,2%	13,3
Croatia*	4.154	48.990	11.793	3.246	781	6,6%	61	57	6,6%	1,9%	14,7
Lithuania*	2.848	42.191	14.814	765	269	1,8%	28	29	-2,2%	3,6%	9,8
Latvia	1.950	27.033	13.863	2.396	1.229	8,9%	22	21	4,1%	0,9%	11,4
Slovenia	2.066	43.000	20.813	3.586	1.736	8,3%	50	48	4,0%	1,4%	24,2
Estonia	1.316	23.615	17.945	1.397	1.062	5,9%	19	18	3,9%	1,3%	14,3
Cyprus*	855	19.571	22.890	1.193	1.396	6,1%	2	2	0,0%	0,2%	2,3
Malta*	460	11.140	24.217	790	1.718	7,1%	5	5	0,0%	0,6%	10,9
New MS	104.179	1.322.853	12.698	84.592	812	6,4%	1.067	1.032	3,3%	1,3%	10,2
EU-28 (EU-15 + new MS)	511.518	15.373.553	30.055	1.506.345	2.945	9,8%	10.114	10.099	0,1%	0,7%	19,8
Switzerland	8.419	601.327	71.425	73.778	8.763	12,3%	462	469	-1,5%	0,6%	54,9
Norway	5.258	354.287	67.381	35.836	6.816	10,1%	180	179	0,9%	0,5%	34,3
Iceland	338	21.696	64.189	1.747	5.169	8,1%	11	11	0,0%	0,6%	32,5
EFTA	14.015	977.310	69.733	111.361	7.946	11,4%	653	659	-0,8%	0,6%	46,6
TOTAL (EU-28 + EFTA)	525.533	16.350.863	31.113	1.617.706	3.078	9,9%	10.768	10.758	0,1%	0,7%	20,5
Turkey <sup>3</sup>	79.815	753.904	9.446	27.917	350	3,7%	N/A	506	N/A	N/A	N/A
TOTAL (EU-28 + EFTA + Turkey)	605.348	17.104.767	28.256	1.645.623	2.718	9,6%	N/A	11.345	N/A	N/A	N/A

<sup>1</sup> France data includes only the Central Laboratory IVD Market.

- The applied exchange rates are the 2017 annual average exchange rates published by The European Central Bank. Applying a single exchange rate to both 2016 and 2015 sales data eliminates possible fluctuations of market size and market growth due to exchange variations. The impact of these fluctuations is shown in the table below.
- During the data collection of 2017 year's figures, the 2016 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 2016. The growth rate between 2017 and 2016 has been calculated using the re-estimated figures.
- The data regarding population, GDP and healthcare expenditure are the latest available from Eurostat, OECD and the World Health Organisation (WHO).

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

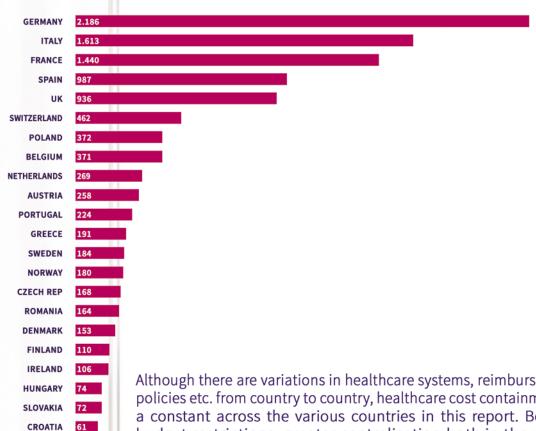
Country	Currency	2017 average Exchange Rate	2016 average Exchange Rate	IVD mkt. 2017	IVD mkt. 2016*	IVD mkt. growth rate 17-16
UK	GBP	1,1413	1,2239	937	985	-4,9%
Sweden	SEK	0,10381	0,10566	184	183	0,5%
Denmark	DKK	0,134433	0,134315	153	150	2,3%
EU-15	EUR	N/A	N/A	9.048	9.136	-1,0%
Poland	PLN	0,2349	0,2292	370	336	10,3%
Romania	RON	0,2189	0,2227	165	168	-1,7%
Czech Rep	CZK	0,038965	0,03699	168	158	6,4%
Hungary	HUF	0,003234	0,003211	74	71	4,2%
Bulgaria	BGN	0,511305	0,511305	30	29	5,2%
Croatia	HRK	0,134	0,1328	61	57	7,5%
New MS	EUR	N/A	N/A	1.066	1.017	4,8%
EU-28 (EU-15 + new MS)	EUR	N/A	N/A	10.115	10.153	-0,4%
Switzerland	CHF	0,9006	0,9174	463	470	-1,4%
Norway	NOK	0,1073	0,1077	180	179	0,5%
Iceland	ISK	0,00806	0,00806	11	11	0,0%
EFTA	EUR	N/A	N/A	654	660	-0,9%
TOTAL (EU-28 + EFTA)	EUR	N/A	N/A	10.769	10.813	-0,4%

 $<sup>2\,\</sup>text{UK}\,data\,reflects\,the\,consolidated\,sales\,of\,the\,participating\,companies\,in\,GDMS,\,plus\,the\,figures\,published\,by\,NHS\,England\,for\,glucose\,test\,strip\,sales\,adjusted\,to\,represent\,the\,whole\,of\,the\,UK.$ 

 $<sup>3\,\</sup>mbox{Turkey}$  figures were not provided for 2017.



# European IVD Market 2017 (million)



SLOVENIA

**BULGARIA** 

LITHUANIA LATVIA

LUXEMBOURG

**ESTONIA** 

**ICELAND** 

MALTA **CYPRUS**  28

11

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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.

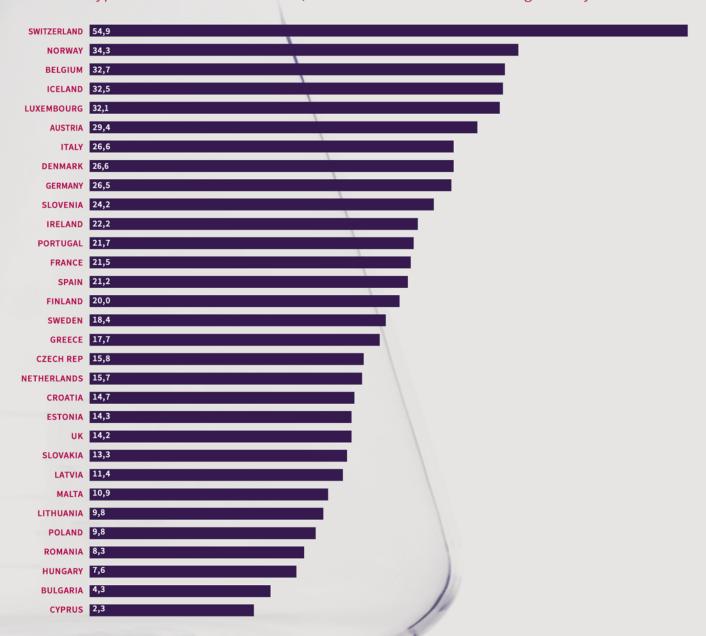
during 2016, the situation overall in 2017 remains unsatisfactory.

While Days Sales Outstanding (DSO) showed some improvement



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 Switzerland is the leading country at 12.3%, followed by France, Germany and the Scandinavian countries. In absolute amounts the healthcare expenditure per capita for Switzerland remains in first position, followed by Norway, Luxemburg, Denmark and Sweden.

The IVD per capita expenditure also shows a wide variation from a low of €2.3 in Cyprus to €54.9 in Switzerland, which remains also the leading country.



"In 2017, the German IVD-Market declined about -2.2%. After many years of a flat market development, the results of 2017 show a distinctive decline of sales. However, the market development differed strongly between the various segments. Laboratory diagnostics (reagents and instruments) continue to increase similarly to the previous years (+1.5%). A major decline can be found for the rapid market where the negative market trend of 2016 continues. While the sales decreased by -2.5% in 2016, the market segment declined even more in 2017 (-8.5%). A large portion of this development continues to be caused by the glucose self-testing market. The market segment decreased by -11.2% in 2017. This is a larger decline compared with 2016 (-1.2%). Several reasons are responsible for this development. First, the restrictive legal framework that forces medical doctors to prescribe generic, low-priced test strips to not overstep their respective budget remains in place. In addition, the shift to new sensor-based technologies for the measurement of glucose continues in Germany. As long as flash glucose monitoring / continuous glucose monitoring is not included in the GIVD classification and due to the current market situation with only a very few number of competitors, the positive development of these technologies cannot be reproduced exactly. The regulatory environment in Germany remains strict. The floating quota percentage for laboratory service fees remains in place and unchanged in 2017. Consequently, price pressure does stay strong in the German IVD-Market. However, despite this various market segments continue to thrive. The sales numbers for the market segment 'Microbiology Reagents' increased by +4.5%, for Infectious Immunology Reagents by 2.0% and for Immunochemistry Reagents by 1.6%." - VDGH, German IVD industry associationn

G E R M A N Y

-2.1% IVD MARKET 2186 M EUR

ITALY

"Italian Stability Law 2017 (Law December 11, 2016, no. 232) and its following legislative update (23 September 2017) have not taken particular decisions for the Italian NHS. In particular the healthcare public expenditure amount has been confirmed but its weight on GDP has decreased to 6.7%, putting at risk the sustainability and quality of the Italian universalistic welfare state. Looking at public procurement, the centralization process is occurring with regional and national bodies managing more than 70% of public purchasing. This trend is creating big issues across the NHS due to the increase of tender size (product range, geographical area, fiscal criteria, etc.) which is reducing competition in the market and to the organizational and functional diversity among regional contract authorities, increasing variability uncertainty for the industries. Within this framework, the medical device market is quite stable at 11 billion euro, 70% of which is public spending for goods and services. Considering only medical devices, Italian expenditure is equal to €5.8 billion, structurally over the 4.4% cap defined at national level and linked to a "payback mechanism" which is creating strong tension and uncertainty across the system. Focusing on the 2017 IVD market, it is quite stable at approximately €1.600 billion with a small increase of 0.4% compared to 2016. Negative results can be highlighted for glucose testing (-2,1%) and infectious immunology (-1,7%). "- ASSOBIOMEDICA, Italian IVD industry association

+0.4% IVD MARKET 1613 M EUR

# FRANCE

"The Central Laboratory IVD French market is estimated at 1.440 billion €, with a non-significant growth of +1% compared to 2016. The Central Laboratory IVD French market has been flat since 2014 with continuous non-significant growth (+0.5% in 2016 vs 2015, +0.1% in 2015 vs 2014), after three years of slight but steady decrease (-0.4% in 2014 and -0.3% in both 2013 and 2012)." - SIDIV, French IVD industry association

+1.1% IVD MARKET 1440 M EUR Z D A D S

"The market remains flat with no clear trends. Mature test market declines due to price reductions and new test incorporation are not enough to create a recognisable trend. Consolidation of laboratories is a trend but there is not too much room for consolidation. Most laboratories already consolidated are looking for economies of scale and homogenization of the region's procedures and technologies. Customers are looking for new approaches to contracts based on risk sharing or value-based considerations. Cost increases for automation are considered in a context of a price driven market, especially in core labs. The introduction of innovative technologies or new tests is very slow due to a very heterogeneous market with 17 autonomous regions, each with different technology incorporation processes and purchase approaches. Continuous monitoring of Glucose is beginning to be reimbursed in some regions subject to individual approval. Other glucose test strip sales suffer a commoditization approach There has been a disappointing evolution of POC which is lacking a clear model of reimbursement."- FENIN, Spanish IVD industry association

+0.2% IVD MARKET 987 M EUR

X N G D O M

"After the 2016 referendum vote to leave the EU, the new Prime Minister, Theresa May, 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. This has complicated negotiations as a troublesome issue is the border between the Republic of Ireland and Northern Ireland which remains part of the United Kingdom. Within this context, the state of the National Health Service has not improved, and forecasts continue to point to a major shortfall in funding in coming years, so some 'remainers' have cried foul at the promises made by those advocating 'Brexit' to contribute to this gap from savings made when leaving the EU. The consolidation of Pathology Services, still seen as a 'back office' function, and therefore cost, has now been further promoted by the findings of another report by Lord Carter and the specific proposal for 29 'hub and spoke' groupings of laboratories, for which a model was presented by NHS Improvement, and NHS Trusts required to respond with their plans to achieve this structure or an acceptable alternative. Some Trusts have already taken this action, others have major challenges to make a viable grouping given geographical and other barriers. Seasonal 'flu contributed to the worst winter for a decade 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



## GREECE

"After nine years with recession in Greece (2008 through 2016) resulting a GDP decrease of 27.4%, the Greek economy expanded by an unadjusted 1,4% (2017 vs 2016) after stalling in 2016 (-0,05% vs 2015). The capital controls that were implemented on 28/6/2015 are looser, but still in place. The Greek IVD market grew in 2017 for the second consecutive time after 2008, by 1.1%, reaching a size of € 191M. In the public sector, which accounts for approximately 65% of the total IVD market in Greece, the Hospital Operating Expenses -which represent 88% of the total available government health care budget- were decreased by 3,2% in 2016 vs. the 2015 expenses. Public procurement, based on tenders and negotiations, is dictated by the Observatory of Prices of the MoH, which continuously pushes prices down, regardless of technical specifications, volumes or method. New legislation concerning procurement in the public sector, was voted and implemented in August 2016, further enhancing the importance of the price criterion over the quality and most economic advantageous offer ones. In the anticipation of the formation of the new Authority which will be responsible for all the tenders, several hospital tenders have been stalled. 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 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. Most of the IVD suppliers still suffer from the losses imposed on 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 have not yet been overcome and have left a lasting effect on the Greek IVD market. DSO decreased from 310 days at the end of 2016 to 200 days at the end of 2017. The improvement was mainly due to the strict supervising by the troika officers. - "SEIV, Greek IVD industry association

+1.1% IVD MARKET 191 M EUR

#### BELGIUM

-0.6% IVD MARKET 371 M EUR "In 2017, the IVD market decreased by -0.46 %, reagents (total) revenues: -0.7 % and Instruments, Consumables, Software: -+0.1 %. Within the national healthcare budget 2017 ( $\leqslant$  24,248 Mio), the Clinical Biology expenditures represent  $\leqslant$  1,300.5 Mio or 5.36% (sum of different tariffs + different lump sums). Here below are some of the most important measurements taken in 2017 (not exhaustive)

- Reimbursement NIPT (Non-Invasive Prenatal Test for trisomy 21) starting from 01.07.2017 (molecular diagnostic test)
- Ministerial Decree of 23/05/2015 regulating the novel medical specialism "clinical geneticist"
- Shift competent authority IVD from SPHI to FAMHP Scientific Public Health Institute
   Federal Agency for Medicines and Health Products
- · New nomenclature for thin layer cervical cytology (discouraging PAP-smear/test)
- $\bullet \ \ Restriction of Toxoplasmosis and cytomegalovirus serology during pregnancy starting 2017, June 1 st ``$

beMedtech, Belgian IVD industry association

# DENMARK

"There is a growth on around 2% in the IVD market in Denmark. The growth is mainly due to increase in the number of tests performed. The test growth volume is estimated to be 5% per year, but due to price erosion the market has only grown by 2%. The reason for the price erosion is the EU tender regulations, which require that most purchases for clinical chemistry laboratories are done through tenders. Point of Care and Molecular purchases are rarely done through tenders. The trends in the market continue to be focused on automation to reduce labour cost and reduction in Turn Around Times. The goal is to reduce the time a patient is hospitalized, which also opens a new market for Point of Care testing and Self testing." - DiaLab, Danish IVD industry association

+2.2% IVD MARKET 153 M EUR

### POLAND

"Compared to previous year, the Polish marked observed the following dynamics:

- Total market +7.6%
- Laboratory market +8.3%
- Clinical chemistry +8.00%
- Genetic testing +20.2%"

MedTech Polska, Polish IVD industry association

+7.6% IVD MARKET 372 M EUR

"The IVD market in Portugal has shown a stable trend since 2015, slightly decreasing in 2017 at -1.3%. Short term tendering and contracts added to political measures to contain costs in Healthcare, specifically with Medical Devices, are leading to high pressure on prices. Market positive developments from organic growth (due to higher life expectancy and the increase in the elderly population) are being compensated by market value decreases with cost measures and high competition. National Health System (NHS) debt to external providers returned to a growing trajectory over 2017, only mitigated by one-off budget injections. 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 and increasing role of 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. On another hand, private labs are suffering pressure as is intention of the Government in place to internalize IVD as much as possible in the public settings. There is a growing patient empowerment and a shift of disease management from reactive to preventive. Public policies are focused at improving screening and integrating hospitals and primary care, while centralizing purchases for the NHS. Discussions are arising on new models of funding healthcare, like value-based purchasing and payments over results in health." - APIFARMA, Portuguese IVD industry association

TOTIOGAL

-1.3% IVD MARKET 224 M EUR

 $\Gamma \cup V \in N \cap V$ 

"One of the highest growths in the last few years, very much driven by Diabetes ( $\pm$ 13.2%), especially by Glucose strips sales ( $\pm$ 13.4%). In fact, the Rapid Tests & POC Market, where performance had been rather low previous year, has returned to growth of  $\pm$ 10.9% in 2017. The same is true of the POC market without diabetes which has improved by  $\pm$ 5.6% as well.

The Laboratory market continues with a positive trend (+3,6%), classically by Immunochemistry Reagents (+2,4%), however the biggest contributor in 2017 was Chemistry/Immunochemistry Instruments, growing +17,9%, apparently due to higher investments in instruments in the Public sector. Previously instrument acquisition was almost only by means of the Reagent Rental model.

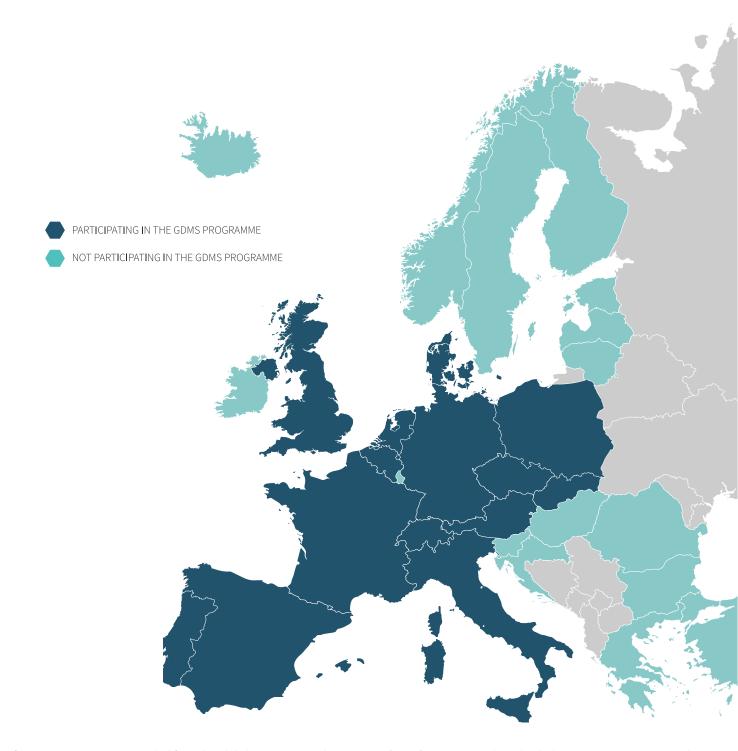
Haemostasis Reagents (Coagulation) continues with the negative trend from the year before - 8,3%. In spite of a rather positive trend on the market, a big increase of appeals in public tenders was recognized in 2017, which very much slowed down replacement of old technology and introduction of a new technology solutions. Some of the tender decisions have already been delayed or postponed for more than one year. "- SIEDMA, Slovenian IVD industry association

+4% IVD MARKET 50 M EUR

# Data Gathering

The results presented above are based on individual estimates made for 28 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 MedTech Europe and the MedTech Europe's Market Research Committee have estimated the IVD market in 15 other countries not participating in the GDMS programme: Bulgaria, Croatia, Cyprus, Estonia, Finland, Greece, Hungary, Iceland, Ireland, Latvia, Lithuania, Malta, Norway, Romania, Slovenia, and Sweden.



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 to an independent auditor, CIP, as based on the Global IVD (former EDMA) 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 (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 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.

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 size 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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