



European IVD Market Statistics Report 2020

Overview

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 2019 and 2018 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.

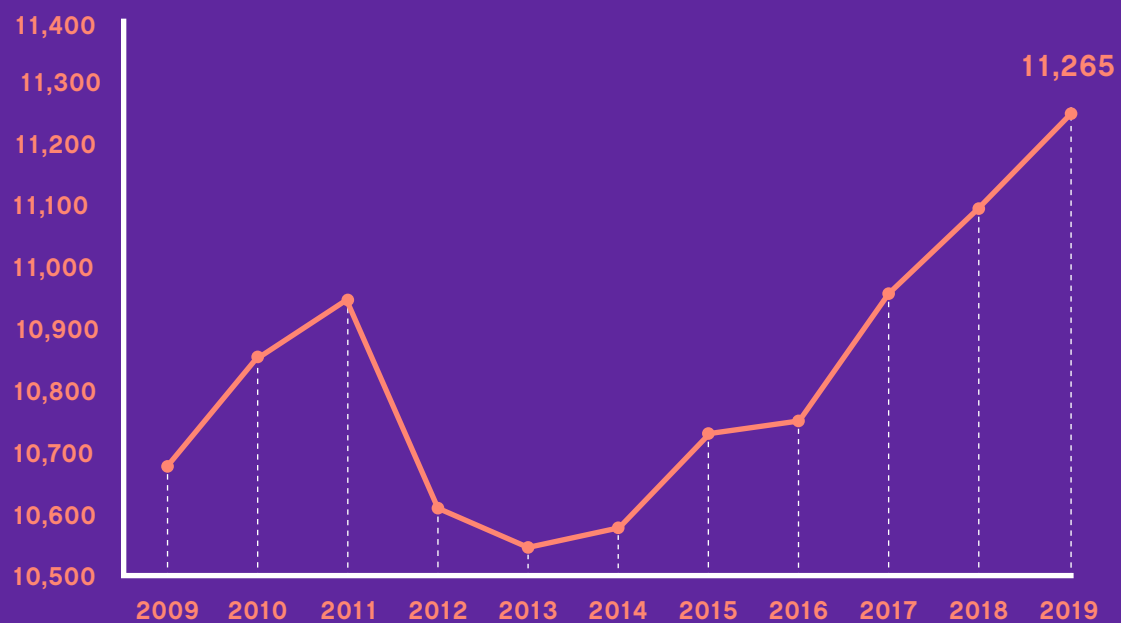
In vitro diagnostics (IVDs) are an essential part of today's healthcare. IVDs are used to diagnose, monitor, screen and assess predispositions to diseases, thereby contributing to the available medical information regarding a patient. By allowing earlier and more targeted treatments, IVDs help to reduce 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 UK are showing slight to moderate growth in 2019 and overall revenues across EU-28 plus EFTA reached €11,265 million, an increase of +1.5%. If changes in the value of non-Euro currencies, are considered the overall change in the Euro value of the European IVD market from 2018 to 2019 is +1.3%.

The IVD revenues in Germany stagnated (-0.4%), further market decrease was seen in the reagents market (-1.2%). In Italy, the IVD market decreased (-2%), with decreased revenues in both clinical chemistry, (-7.6%) and haematology, (-2.7%). From the largest five markets, the UK is experienced the highest increase of +3.1%, largely due to increase in instruments and consumables, infectious disease testing, and nucleic acid testing systems. In Spain, the IVD market increased by +2.8% due to growth in immunochemistry, micro and infectious diseases segments. After stagnation in 2015 and 2016, the French IVD market registered a third year of slight growth of +0.3%. 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. The Greek market marked an increase of + 3.7%, the highest growth since 2008. On the other hand, Portugal reported a -1.5% decrease in IVD expenditure.

In the newer EU member states, IVD expenditure averaged 1.2% 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 €11.3 per capita compared to €23 in the EU-15. Growth in those states is at +6.4% compares to +0.8% in the EU-15 states.

EUROPEAN IVD MARKET REVENUES (MILLION €)



IVD Market Statistics

Countries	Population	GDP	GDP / capita	THE	THE / capita	THE as % GDP	IVD mkt. 2019	IVD mkt. 2018	IVD mkt. growth rate 19-18	IVD mkt. / THE	IVD mkt. / capita
	1000	Mio €	€	Mio €	€	%	Mio €	Mio €	%	%	€
	Eurostat 2019			Eurostat 2018			Source MedTech Europe				
Germany	83.019	3.449.050	41.545	383.636	4.627	11,5%	2.161	2.170	-0,4%	0,6%	26,0
France ¹	67.013	2.425.708	36.198	265.764	3.969	11,3%	1.623	1.619	0,3%	0,6%	24,2
UK ²	66.647	2.522.713	37.852	242.300	3.646	10,0%	1.042	1.011	3,1%	0,4%	15,6
Italy	60.360	1.789.747	29.651	153.085	2.534	8,7%	1.556	1.588	-2,0%	1,0%	25,8
Spain	46.937	1.244.772	26.520	108.110	2.310	9,0%	1.033	1.004	2,8%	0,9%	22,0
Netherlands	17.282	810.247	46.883	77.202	4.480	10,0%	294	286	2,7%	0,4%	17,0
Greece	10.725	183.414	17.102	14.251	1.328	7,7%	213	198	7,5%	1,4%	19,8
Portugal	10.277	213.301	20.756	19.303	1.877	9,5%	226	229	-1,5%	1,2%	22,0
Belgium	11.456	476.203	41.570	47.417	4.150	10,3%	399	386	3,3%	0,8%	34,8
Sweden	10.230	474.468	46.379	51.296	5.041	10,9%	187	179	4,5%	0,3%	18,2
Austria	8.859	397.575	44.879	39.791	4.501	10,3%	268	262	2,3%	0,7%	30,3
Denmark	5.806	312.747	53.865	30.450	5.256	10,1%	155	151	2,8%	0,5%	26,7
Finland	5.518	240.556	43.595	21.117	3.829	9,0%	119	120	-1,2%	0,6%	21,5
Ireland	4.904	356.051	72.601	22.452	4.613	6,9%	126	122	3,7%	0,5%	25,7
Luxembourg	614	63.516	103.465	3.174	5.221	5,3%	19	19	0,0%	0,6%	30,9
EU-15	409.646	14.960.069	36.520	1.479.349	3.611	9,9%	9.419	9.343	0,8%	0,6%	23,0
Poland	37.973	532.329	14.019	31.502	830	6,3%	394	377	4,4%	1,2%	10,4
Romania	19.414	223.337	11.504	11.371	584	5,6%	195	180	8,1%	1,6%	10,0
Czech Rep	10.650	223.945	21.028	15.872	1.493	7,7%	182	158	15,0%	1,0%	17,1
Hungary	9.773	146.062	14.946	8.964	917	6,7%	82	79	5,1%	0,9%	8,4
Bulgaria	7.000	61.240	8.748	4.121	587	7,4%	30	32	-7,4%	0,8%	4,3
Slovakia	5.450	93.865	17.222	5.991	1.100	6,7%	77	76	1,9%	1,3%	14,2
Croatia	4.076	54.238	13.306	3.524	862	6,8%	67	65	4,4%	1,8%	16,5
Lithuania	2.794	48.797	17.464	2.973	1.061	6,6%	31	29	9,3%	1,0%	11,3
Latvia	1.920	30.463	15.867	1.804	936	6,2%	30	24	24,3%	1,3%	15,5
Slovenia	2.081	48.393	23.256	3.797	1.831	8,3%	52	52	0,1%	1,4%	25,0
Estonia	1.325	28.112	21.220	1.735	1.312	6,7%	21	21	-0,8%	1,2%	16,1
Cyprus	876	22.287	25.445	1.431	1.645	6,8%	10	10	5,3%	0,7%	11,4
Malta	494	13.462	27.276	1.110	2.290	9,0%	5	5	0,0%	0,5%	10,1
New MS	103.826	1.526.531	14.703	94.194	907	6,2%	1.177	1.108	6,3%	1,2%	11,3
EU-28 (EU-15 + new MS)	513.472	16.486.600	32.108	1.573.543	3.065	9,5%	10.596	10.451	1,4%	0,7%	20,6
Switzerland	8.545	653.471	76.478	70.902	8.327	11,9%	473	462	2,2%	0,7%	55,3
Norway	5.328	360.301	67.621	36.971	6.960	10,1%	185	178	3,8%	0,5%	34,7
Iceland	357	21.635	60.604	1.862	5.280	8,5%	11	11	0,0%	0,6%	30,8
EFTA	14.230	1.035.407	72.764	109.735	7.712	10,6%	668	651	2,6%	0,6%	47,0
TOTAL (EU-28 + EFTA)	527.701	17.522.007	33.204	1.683.278	3.190	9,6%	11.265	11.102	1,5%	0,7%	21,3
Turkey	82.004	679.510	8.286	27.701	338	4,1%	N/A	645	N/A	2,3%	N/A
TOTAL (EU-28 + EFTA + Turkey)	609.705	18.201.518	29.853	1.710.979	2.806	9,4%	N/A	11.748	N/A	0,7%	N/A

1 France data includes only the Central Laboratory IVD Market.

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.

The applied exchange rates are the 2019 annual average exchange rates published by The European Central Bank. Applying a single exchange rate to both 2019 and 2018 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 collection of 2019 year's figures, the 2018 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 2018. The growth rate between 2019 and 2018 has been calculated using the re-estimated figures.

The data regarding population, GDP and healthcare expenditure are the latest available from Eurostat.

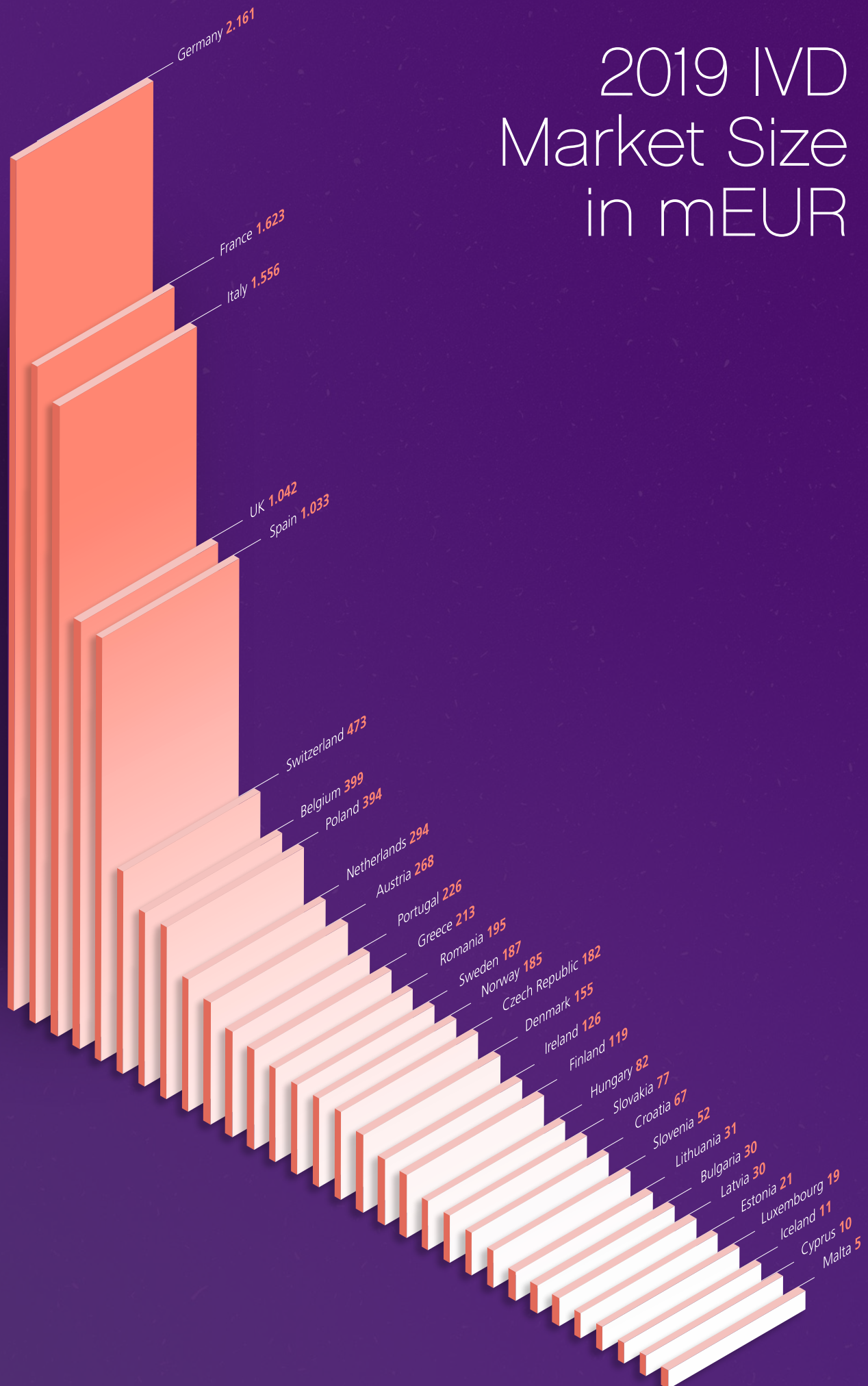
IVD Market Size in EUR (using actual exchange rates)

Country	Currency	2019 average Exchange Rate	2018 average Exchange Rate	IVD mkt. 2019 Mio LC	IVD mkt. 2018 Mio LC	IVD mkt. 2019 Mio €	IVD mkt. 2018 Mio €	IVD mkt. growth rate 19-18
UK	GBP	1,1399	1,1304	914	887	1.042	1.002	3,9%
Sweden	SEK	0,09446	0,09752	1.975	1.891	187	184	1,2%
Denmark	DKK	0,133939	0,134171	1.159	1.128	155	151	2,5%
EU-15	EUR			N/A	N/A	9.419	9.341	0,8%
Poland	PLN	0,2327	0,2347	1.678	1.608	390	377	3,5%
Romania	RON	0,2107	0,2149	906	840	191	180	5,7%
Czech Rep	CZK	0,03896	0,03899	4.664	4.057	182	158	15%
Hungary	HUF	0,003075	0,003137	26.739	25.681	82	81	2,1%
Bulgaria	BGN	0,511305	0,511305	60	64	30	32	-7,4%
Croatia	HRK	0,134	0,134	502	481	67	65	4,4%
New MS	EUR			N/A	N/A	1.169	1.110	5,3%
EU-28 (EU-15 + new MS)	EUR			N/A	N/A	10.588	10.451	1,3%

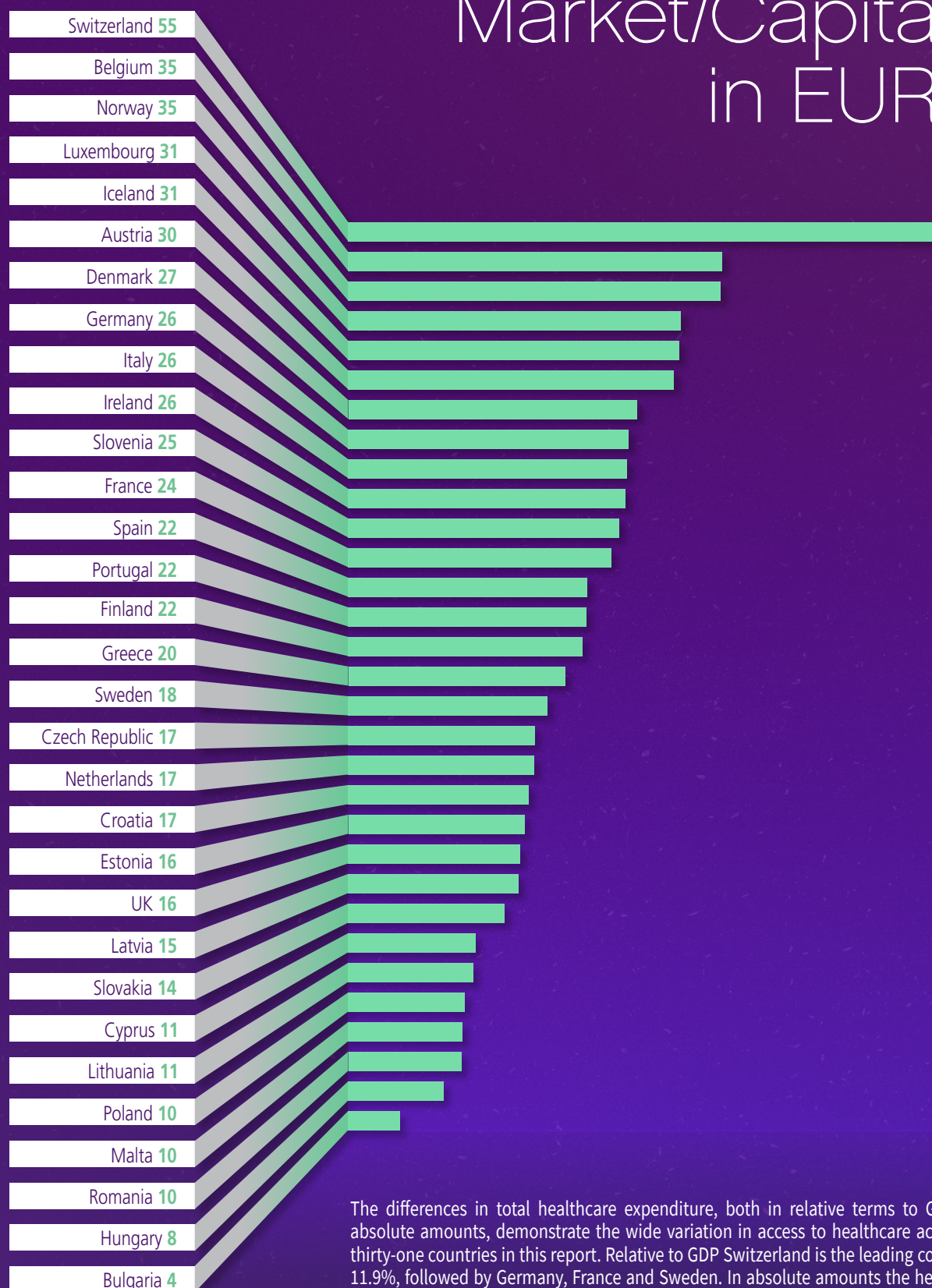
Country Specific Data

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. The overall situation with Sales Outstanding (DSO) in 2019 remains unsatisfactory.

2019 IVD Market Size in mEUR



2019 IVD Market/Capita in EUR



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 11.9%, followed by Germany, France and Sweden. In absolute amounts the healthcare expenditure per capita Switzerland remains in first position, followed by Norway, Iceland, Denmark, Luxembourg, and Sweden.

The IVD per capita expenditure also shows a wide variation from a low of €4.2 in Bulgaria to €55.2 in Switzerland, which remains also the leading country.

Germany -0.4% IVD MARKET 2161 M EUR

"The German IVD market continues with a slight decrease. The total IVD market 2019 is estimated at 2.161 billion euros. This represents a market decline of 0.4% compared to the previous year. The reagents market fell by 1.2%, while the market for instruments (including services, spare parts and supporting software) grew by 4.2%. Looking at the different market segments the laboratory market (reagents and instruments) grew by 2.0%. Some of the effects of the 2018 laboratory reform are now probably priced in. This "reform" essentially involved stricter budgeting by office-based physicians. After leaving this through immunochemistry, microbiology and infectious immunology were the growth drivers in 2019. In contrast, the rapid test market shows a decline of 5.6%. The gap in growth in these market segments has widened in 2019. Again, the decline in the market for blood glucose test strips (- 6.4%) dominates the entire rapid test market. However, this should be offset by significant growth in sensor-based glucose measurement (FGM, CGM) which cannot be shown in the data. From 2020, the total IVD market will additionally be reported without the diabetes self-management segment. This further increases the informative value of the data reports." - [VDGH, German IVD industry association](#)

Italy -2.0% IVD MARKET 1556 M EUR

Italian IVD market remains almost unchanged with slight decline of 2% during 2019 and only 0.5% if we exclude glucose tests. Compared to the previous year, the 2019 clinical chemistry sales decreased by 7.6%, mainly due to contraction of the public healthcare expenditure. Public buyers followed harsh cost containment strategies, and an ongoing reorganisation taking place in the public labs. The immunochemistry market grew by 3.9%, caused largely by increased testing in hormone and cardiac markers, as well as tests for autoimmune diseases and cancer. The haematology segment decreased by 2.7%, while a 6.9% drop of sales occurred in microbiology, infectious diseases, and genetic testing. In 2019, strategies by the Regions continued to be focused on controlling public expenditure for IVDs. The lines of these policies were: (i) usually many biddings were equal as in the previous years; (ii) many Regions approved laws to reduce the number of tests in private labs (in many cases, a patient could have tests taken in a private labs but still reimbursed by the NHS), and such tests have to be done by only public labs (usually with long queues); (iii) the Government was not able to design its own governance strategies on medical devices and IVD, and the goal was to reduce it.

[Confindustria Dispositivi Medici, Italian IVD industry association](#)

Spain +2.8% IVD MARKET 1033 M EUR

"Mainly price-driven market and mild growth thanks to innovative tests. Growth in immunochemistry, micro and infectious diseases. Aggregated purchasing for the region and consolidation of laboratories remains a strong tendency but there is not too much extra-room for consolidation. Most laboratories have already consolidated and are looking for economies 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 this kind of contracts is still only testimonial. Costs are increasing for automation and digitalization that reach almost every lab. Very automated market. 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. Innovation is accepted but in a scenario where prices remains blocked and cost increases are seldom accepted. Continuous monitoring of Glucose is reimbursed in all regions subject to individual approval. Other glucose test strips suffers a commoditization approach. Evolution of POC lacking of a clear model of reimbursement and we don't see a significant improvement in the near future."

[FENIN, Spanish IVD industry association](#)

France **+0.3% IVD MARKET 1624 M EUR**

"The Central Laboratory IVD French market is estimated at 1.624 billion €, with a growth of +0.3% compared to 2018. 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 **+3.1% IVD MARKET 1042 M EUR**

"The referendum result of 2016 to leave the European Union resulted in the resignation of David Cameron as "The UK IVD market grew by 3.1% during 2019, of which a significant component was instruments and consumables. This could be in part due to increased reporting of these groups. Reagent revenues increased by 1.1% and there was particularly strong growth in Infectious Disease testing revenues. It is difficult to avoid commenting on 2019 without mentioning the current situation in the midst of the 2020 Covid-19 epidemic, but as the Influenza season was mild, it may have contributed to a lack of preparedness for mass testing later. At the time, however, the major concern was still Brexit and its likely impact on supply chains and market access. As expected, nucleic acid testing systems continue to grow strongly, by about £12m (17%) over 2018, and multiple target NAT infectious disease systems grew by 32%. Some individual tests declined surprisingly, such as Vitamin D, while allergy and autoimmune testing saw double digit percentage growth. Overall, the UK still spends a very low amount per capita on IVD testing."

BIVDA, British IVD industry association

Poland **+4.4% IVD MARKET 394 M EUR**

"Compared to the previous year, the Polish market observed an increase of +4.4%."

MedTech Polska, Polish IVD industry association

Portugal **1.5% IVD MARKET 226 M EUR**

"IVD market in Portugal has been quite stable, showing a negative development of -1.5% when compared with 2018. The market excluding glucose strips, has been stable, with a growth of 0.4%. The cause of the -1.5% market growth is that we are seeing a shift towards new technologies. In 2019, test strips declined around 4%. Short term tendering and contracts adding to political measures to contain costs in Healthcare, specifically with Medical Devices, leads to high pressure on prices. Slight market positive development from organic growth (higher life expectancy and increase in elderly population) is being compensated by market value decrease with cost measures and aggressive competitive pressure. Public funding is leaning towards more cost-effective and integrated care, with an increasing role of insurance companies. Health insurance continues to gain relevance with ~25% of population insured (growth 4.5%) and a growing number of private hospitals competing aggressively to gain MS. Lab consolidation seen in the past has slowed down with stabilization of number of labs in the country. We've 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. NHS purchasing centralization continues to be discussed although not yet applied to IVD. Discussions are arising on new models of funding healthcare, like value-based purchasing and payments over results in health."

APIFARMA, Portuguese IVD industry association

Greece +7.5% IVD MARKET 213 M EUR

“2019 was the first full year during which the Greek Government was able to define its fiscal policy outside the fiscal adjustment programmes since 2010. The Greek economy grew for the third consecutive year, with 1.9% GDP growth compared to 2018. The Greek IVD market grew by 7.5% in 2019, for the fourth consecutive time since 2008, reaching a size of € 213M. This growth is driven mainly from the public sector, which represents 67% of the Greek IVD market. The remaining 33% corresponds to the private sector. Finally, for the total IVD Market, DSO were approximately 230 days during 2019.”

SEIV, Greek IVD industry association

Slovenia +0.1% IVD MARKET 52 M EUR

“The market stayed at last year's level, only +0.1 % growth. The reason is mainly the decline of the Rapid testing and Diabetes Care market by almost -4 % and slowing down of the Laboratory market growth. Reagents sales were declining approximately -2 % due to Clin Chemistry (-3 %), Haematology/ Haemostasis (- 4%), and a big drop in Infect. Immunology (- 14 %), all being partially compensated by Immunology Reagents sales by + 6 %. To last year's outstanding contribution of the Instruments sales to the market value, the trend continued by + 8 % growth in 2019 (importantly by Immunochemistry & Infectious Immunology Instruments) and after-sales Service. As the public procurement system is still very much based on price, no significant increase in the market value is expected.”

SIEDMA, Slovenian IVD industry association

Austria +2.3% IVD MARKET 268 M EUR

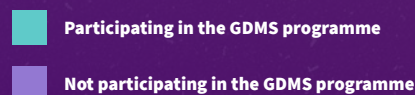
“In 2019, the Austrian IVD market grew by 2.3%, reaching a market size of 268 M Euros.”

AUSTROMED, Austrian IVD industry association

Slovakia +1.9% IVD MARKET 77 M EUR

“IVD market in Slovakia has been quite stable, showing a growth of 1.9 % when compared with 2018, mainly caused by NAT testing in Blood Banks.”

SEDMA, Slovakian IVD industry association



Data Gathering

The results presented above are based on individual 2019 estimates made for 28 countries, comprising of the EU countries, EFTA countries and Turkey:

- 13 countries are participating in the Global Diagnostic Market Statistics (GDMS, former EDMS) programme: Austria, Belgium, Czech Republic, 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 17 other countries not participating in the GDMS programme: Bulgaria, Croatia, Cyprus, Denmark, Estonia, Finland, Greece, Hungary, Iceland, Ireland, Latvia, Lithuania, Malta, Norway, Romania, Slovenia, 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 Classification (GIVD). 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 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 www.medtecheurope.org.

For more information

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