

European
IVD Market
Statistics
Report



2022

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 **2021 and 2020 data**. Macroeconomic and healthcare data are also included for the EU27-member states plus the European Free Trade Association members (EFTA) –Switzerland, Norway and Iceland, and Switzerland, as well as for the United Kingdom and Turkey.

In vitro diagnostics (IVDs) are an essential part of today's healthcare. **Results of in vitro testing influence as many as 70% of clinical decisions, while IVDs account for just 1% of total healthcare expenditure in the EU-27, UK and EFTA.** They play a vital role in in the response to COVID-19. A critical element for combatting the COVID-19 pandemic is to have suitable diagnostic tests available. Furthermore, 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.

Since 2013, the IVD market has been stagnant with slight growth. In 2020, however, due to the COVID-19 pandemic and the high demands for SARS-Cov-2 testing, the IVD market has experienced an increase of + 25,4%. In 2021, we witness an unprecedented record growth of 41.2%. Overall revenues across EU-27, UK and EFTA reached €20,670 million. When looking beyond the COVID-19 related diagnostics and comparing to 2020, there have been clear signs of recovery in most tests in the other IVD segments such as clinical chemistry, immunology, and haematology across the countries.

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 Germany is the leading country at 13.2%, followed by the UK, Austria, Switzerland and Sweden. In absolute amounts the healthcare expenditure per capita Switzerland is in first position, followed by Germany, Austria, Slovakia, Denmark, Norway and Iceland. The IVD per capita expenditure also shows a wide variation from a low of €7.2 in Bulgaria to €88.9 in Switzerland, which remains also the leading country.

The European IVD Market



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IVD Market Statistics

Countries	Population 2021	GDP 2021	GDP / capita 2021	THE 2021 (or latest availiable)	THE / capita	THE as % GDP	IVD mkt. 2021	IVD mkt. 2020	IVD market growth rate 21-20	IVD market / THE 2021	IVD mkt / capita 2021
	1000	Mio €	€	Mio €	€	%	Mio €	Mio €	%	%	€
	Source: Eurostat			Source: OECD			Source MedTech Europe				
Germany	83.155	3.601.750	43.290	457.232	5.499	12,7%	6.301	3.051	106,5%	1,4%	75,8
France ¹	67.657	2.500.870	36.660	307.785	4.549	11,2%	2.610	2.140	22,0%	0,8%	38,6
Italy	59.236	1.782.050	30.150	167.855	2.834	9,4%	2.071	1.780	16,3%	1,2%	35,0
Spain	47.399	1.206.842	25.500	120.203	2.536	10,0%	1.727	1.514	14,1%	1,4%	36,4
Netherlands	17.475	856.356	48.840	96.498	5.522	10,4%	504	365	38,2%	0,5%	28,8
Greece	10.679	181.675	17.010	15.720	1.472	8,7%	412	254	62,1%	2,6%	38,6
Portugal	10.298	214.471	20.840	23.686	2.300	11,0%	491	401	22,6%	2,1%	47,7
Belgium	11.555	502.312	43.340	49.293	4.266	9,8%	428	372	14,8%	0,9%	37,0
Sweden	10.379	537.310	51.590	60.669	5.845	11,3%	253	239	5,7%	0,4%	24,4
Austria	8.933	406.149	45.370	49.024	5.488	12,1%	568	480	18,3%	1,2%	63,6
Denmark	5.840	336.719	57.520	36.411	6.235	10,8%	333	175	90,1%	0,9%	57,0
Finland	5.534	251.367	45.360	22.685	4.099	9,0%	159	132	20,7%	0,7%	28,7
Ireland	5.006	426.283	84.940	28.361	5.665	6,7%	232	151	53,6%	0,8%	46,3
Luxembourg	635	72.295	112.780	3.683	5.802	5,1%	30	21	45,0%	0,8%	48,0
Poland	37.840	574.772	15.060	37.879	1.001	6,6%	493	442	11,6%	1,3%	13,0
Romania	19.202	240.154	12.560	13.496	703	5,6%	240	218	10,0%	1,8%	12,5
Czechia	10.702	238.238	22.270	20.526	1.918	8,6%	267	178	49,5%	1,3%	24,9
Hungary	9.731	153.759	15.840	9.766	1.004	6,4%	107	81	32,6%	1,1%	11,0
Bulgaria	6.917	71.077	10.330	5.211	753	7,3%	50	35	41,1%	1,0%	7,2
Slovakia	5.460	98.523	18.110	6.686	1.225	6,8%	335	97	244,9%	5,0%	61,3
Croatia	4.036	58.254	15.020	3.901	967	6,7%	83	67	25,0%	2,1%	20,7
Lithuania	2.796	56.179	20.000	4.349	1.555	7,7%	58	37	55,8%	1,3%	20,6
Latvia	1.893	33.696	17.890	2.168	1.145	6,4%	49	36	37,7%	2,3%	25,9
Slovenia	2.109	52.208	24.770	4.762	2.258	8,6%	100	62	60,8%	2,1%	47,3
Estonia	1.330	31.445	22.580	2.289	1.721	7,3%	40	26	51,5%	1,7%	30,1
Cyprus	896	24.019	26.680	1.750	1.953	7,3%	15	10	45,0%	0,9%	16,9
Malta	516	14.681	28.310	1.255	2.432	8,5%	8	6	45,0%	0,6%	15,5
EU27	447.207	14.523.453	912.610	1.553.143	80.747	10,5%	17.963	12.370	45,2%	1,2%	40,2
Switzerland	8.670	676.775	77.750	77.187	8.903	11,4%	771	514	49,9%	1,0%	88,9
Norway	5.391	407.533	75.360	41.120	7.627	10,1%	290	168	72,7%	0,7%	53,8
Iceland	369	21.653	58.130	2.079	5.638	9,6%	18	12	47,3%	0,9%	48,3
EFTA	14.430	1.105.962	211.240	120.387	22.168	10,9%	1.079	694	55,4%	0,9%	74,7
UK ²	67.281	2.555.065	37.976	321.505	4.779	12,6%	1.628	1.319	23,4%	0,5%	24,2
TOTAL (EU27, EFTA,UK)	528.919	18.184.480	1.161.826	1.995.036	107.693	10,8%	20.670	14.384	43,7%	1,0%	39,1
Turkey	83.614	689.547	8.247	22.719	272	3,3%	712	497	43,4%	3,1%	8,5
TOTAL (EU27, EFTA, UK,Turkey)	612.533	18.874.026	1.170.073	2.017.755	107.965	10,5%	21.382	14.880	43,7%	1,1%	34,9

The applied exchange rates are the 2021 annual average exchange rates published by The European Central Bank. Applying a single exchange rate to both 2021 and 2020 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 2021 year's figures, the 2020 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 2020. The growth rate between 2021 and 2020 has been calculated using the re-estimated figures. The 2021 data regarding population and GDP are the latest available from Eurostat. The figures regarding healthcare expenditure are the latest available from OECD.

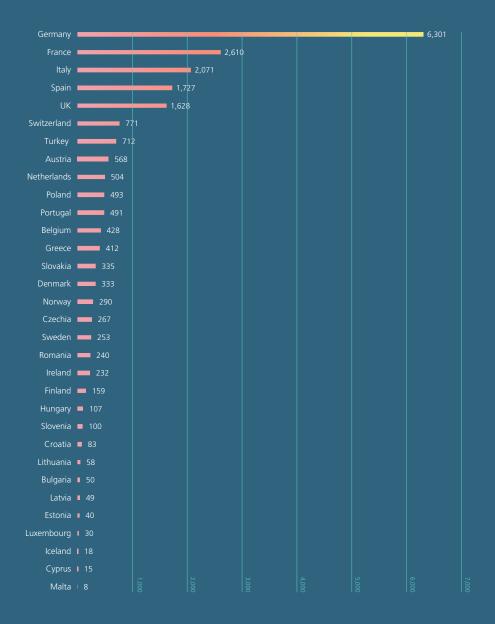
IVD Market Size in EUR (using actual exchange rates)

Country	Currency	2021 Exchange Rate	2020 Exchange Rate	IVD market 2021	IVD market 2020	IVD market 2021	IVD market 2020	IVD market growth rate 21-20
		Average	Average	Mio LC	Mio LC	Mio €	Mio €	%
Poland	PLN	0,2191	0,2252	2.249	2.015	493	454	8,6%
Romania	RON	0,2032	0,2067	1.181	1.054	240	218	10,2%
Czech Rep	CZK	0,03901	0,03783	6.837	4.574	267	173	54,1%
Hungary	HUF	0,00279	0,002849	38.392	29.106	107	83	29,2%
EU27	EUR				N/A	17.963	12.379	45,1%
UK	GBP	1,1622	1,1248	1.401	1.135	1.628	1.277	27,5%
TOTAL (EU27, EFTA,UK)	EUR				N/A	20.670	14.350	44,0%
Turkey	TRL	0,09748	0,12623	7.307	5.094	712	643	10,8%
TOTAL (EU27, EFTA, UK, Turkey)	EUR				N/A	21.383	14.993	42,6%

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.

IVD Market Size 2021 (million EUR)



IVD Market per Capita 2021 (EUR)



SARS-Cov-2 Tests: Volumes

Country	Total Tests 2021	Total Tests 2020	Growth rate 21-20					
Source: ECDC; *Our World in Data								
United Kingdom*	343.554.199	48.972.436	602%					
France	148.436.784	33.651.450	341%					
Austria	115.889.875	3.747.074	2993%					
Italy	114.406.110	20.887.600	448%					
Greece		3.432.711	2952%					
Denmark	95.106.382	10.576.739	799%					
Turkey*	94.520.585	24.464.277	286%					
Germany	57.414.318	36.088.129	59%					
Spain	46.894.218	21.486.152	118%					
Czechia	41.832.831		783%					
Netherlands	29.968.706	8.372.650	258%					
Portugal	20.937.405	5.724.026	266%					
Poland	20.019.974	7.886.328	154%					
Cyprus	16.727.060	939.253	1681%					
Romania		1.940.112	539%					
Slovenia		755.813	1497%					
Switzerland*		3.288.431	237%					
Slovakia		1.256.833	779%					
Sweden		4.093.604	162%					
Norway	10.052.849	3.069.032	228%					
Ireland	7.625.591	2.472.349	208%					
Belgium	6.324.519	7.010.457	-10%					
Bulgaria	6.276.243		474%					
Finland		2.512.145	149%					
Croatia	5.194.645	1.084.453	379%					
Lithuania	2.916.002	1.577.134	85%					
Hungary	2.798.321	1.799.526	56%					
Luxembourg	2.168.275		31%					
Estonia	1.881.816	550.121	242%					
Latvia	1.114.303	475.460	134%					
Malta	1.023.883	527.375	94%					
Iceland	944.683	429.819	120%					
Total	1.362.384.517	266.558.601	411%					

ITALY IVD MARKET 2,071 mEUR +16.3%

"The IVD Italian market, in 2021 recorded an increase of 16.3%. The growth, for almost the totality, is to be attributed to the COVID-19 diagnostics. Looking at the market data, excluding COVID-19 diagnostics and glucose tests, we record an even higher growth of 19.4%. In addition to the increase in COVID-19 related turnover, this market growth is due to the the gradual reopening of all health services which allowed Laboratory Diagnostics to resume its normal activities (hospital and territorial) after almost a year of total closure. In addition, in 2021, laboratory activities began to recover the enormous accumulation of health services not provided in the previous year. The latter will certainly further affect overall growth. The year 2020 is certainly not comparable with any other year. The serious economic crisis due to the almost total closure of all activities, has in fact generated, in 2021, a "rebound effect" that has led to the results achieved. If we compare the results of 2021 to 2019 (pre-pandemic), the overall result (excluding COVID-19 diagnostics) would certainly be more truthful than the country system and in this specific case of Laboratory Diagnostics (+1.7%)."

Confindustria Dispositivi Medici, Italian IVD industry association

UNITED KINGDOM IVD MARKET 1,628 mEUR +23.4%

"In the UK, dramatic reductions in non-Covid testing activity were evidenced in 2020 by reductions in revenue, such as -20% for Clinical Chemistry excluding Rapid Tests, this activity has recovered significantly in 2021 (+20%). Nucleic Acid Testing and Immunoassay are strongly boosted by Coronavirus testing, as is Rapid Testing (mainly antigen tests for current infection). Coronavirus testing has grown from zero in 2019 to almost one quarter of the total UK IVD market in 2021, without counting non-participant company supply via government contracts, for which we have no reliable estimates. Core laboratory reagents, instruments & consumables market revenues recovered a further £66m (+16%). Microbiology revenues decreased by £12m. The decrease was due mainly to a drop of -£11m due to transport media, as PCR testing requirements stabilised."

BIVDA, British IVD industry association

GERMANY

IVD MARKET 6,301 mEUR

+106.5%

"For the second time in a row, the German IVD market has reached record volumes. The background is the ongoing COVID-19 pandemic. Comprehensive testing is a central component of the German government's health policy strategy to combat the pandemic and protect vulnerable groups from infection. In this respect, the German IVD market has become to a large extent a political market in 2021.

The IVD market in 2021 is estimated to have a total volume of 6.3 billion euros. Of this, 4.1 billion euros (65 %) will be accounted for by Coronavirus testing and 2.2 billion euros (35 %) by other diagnostics.

The market volume doubled compared to 2020 (+106.5 %). While growth for all Coronavirus testing was extremely dynamic (+367 %), other diagnostics developed flat (+1.2 %). The biggest growth driver in 2021 was Coronavirus rapid testing. With a volume of €3.67 billion, this market segment alone is significantly larger than the entire pre-pandemic IVD market. As a result of the slowdown in infections, declining trends for 2022 are already clearly discernible. In non-Covid diagnostics, the area of clinical chemistry has recovered. The same applies to haematology/histology/ cytology. Microbiology, on the other hand, recorded market declines for the second time in a row. The development of blood glucose self-testing is also dampening. This market lost 7.2 per cent compared to the previous year, but the decline in sales has slowed down. The shift to sensor-based measurement systems continues to play a decisive role here."

VDGH, German IVD industry association

FRANCE

IVD MARKET 2,610 mEUR

+22%

"The Central Laboratory IVD French market (excluding diabetes) is estimated at 2,610 million Euro, with a growth of +22% compared to 2020. This increase (14.4%) is driven by SARS-CoV-2 products and to recovery of pre-Covid lab activity (+7.6%)."

SIDIV, French IVD industry association

BELGIUM

IVD MARKET 428 mEUR

+14.8%

"The IVD market in Belgium reached 428 million EUR with a growth of 14.8% compared to 2020. In 2021, the expenses in the hospitals and ambulant setting have increased vs. 2020 (in 2020 Covid had a major impact) with more hospitalisations and consultations, therefore more IVD tests were done."

beMedTech, Belgian IVD industry association.

PORTUGAL

IVD MARKET 491 mEUR

+22.6%

"COVID-19 had a big impact on the IVD market, according to our estimation the Sars-CoV-2 reagents represented around 45% of the total IVD sales in Portugal in 2021. In 2020, the country focus was on the COVID-19 pandemic, and we had a decrease on the routine testing with around -8%. In 2021, mainly during the second half of the year, the routine lab testing recovered, and the patients had the possibility to start again visits to the health institutions. The focus of care was not only COVID-19 and due to this fact, the turnover for the other IVD segments was aligned with 2019 figures."

APIFARMA, Portuguese IVD industry association

POLAND

IVD MARKET 493 mEUR

+11.6%

"The year 2020 was a critical one for the Polish healthcare system. Closing hospital wards, postponing treatments, and creating more beds for COVID-19 patients was pivotal. In 2021, the pandemic is slowly being brought under control and delays in overdue services are being compensated. Market increase has been shown in clinical chemistry, immunology, haematology and microbiology. Virology research is at its peak in 2021."

MedTech Polska, Polish IVD industry association

SPAIN IVD MARKET 1,727 mEUR +14.1%

"In 2021, the Spanish market is still under the strong influence of COVID-19 and the related tests. Development of biomarkers and molecular test (not only PCR) for other parameters has also been observed. The centralisation trend for public and private labs remains high but there is not a lot of room for further centralisation. Furthermore, big tenders covering whole region and centralised per provinces and with very long execution periods superior to six years has been registered. Declining or stagnating point of care testing is seen due to the lack of reimbursement except for diabetes testing. In certain cases, type 2 insulin dependent patients could be candidates for continuous glucose monitoring. We witness that robotisation is reaching not only the very big labs but also many medium size ones.

IVDs are now recognized as a key player in medicine both for public and politicians. There has been major investment in human resources and instrumentation in most laboratories but there is uncertainty regarding the future of IVD market once the pandemic is now under control. The best perception of added value is of microbiology and anatomic pathology departments contribution."

FENIN, Spanish IVD industry association

AUSTRIA IVD MARKET 568 mEUR +18.3%

"The market dynamic, in 2021, was again determined mostly by SARS-CoV-2 Testing (PCR and Antigen testing) due to the very extensive testing strategy by the government. Many companies, not participating to the market statistics programmes entered the market. Thus, making it difficult to estimate the total COVID-19 related market. The classical laboratory market recovered and went basically back to the pre-pandemic level with a small increase. "

AUSTROMED, Austrian IVD industry association

GREECE IVD MARKET 412 mEUR +62.1%

"After a substantial decrease in GDP in 2020 due to the COVID-19 pandemic (-9.0 % based on latest data), in 2021 Greece is again on a growth trajectory, with a +8.3% increase in GDP year-on-year. In 2021, the total IVD Market grew by 62.1% compared to 2019, mainly driven by SARS-CoV-2 revenues of 180M Euro compared to 50M Euro in 2020. The Greek IVD Market, excluding coronavirus testing, grew by 13.7%, driven by growth across all the traditional IVD categories - clinical chemistry, haematology, immunology excluding coronavirus testing. "

SEIV, Greek IVD industry association.

CZECH REPUBLIC IVD MARKET 267 mEUR +49.5%

"The market growth observed in 2021 in the Czech Republic has been driven by infectious disease testing +39.8%, due to the COVID-19 pandemic, as well as related increased revenues in services +15,6% and instruments +2.4% compared to 2020. Furthermore, market recovery is shown also in in microbiology 14%, clinical chemistry 6.3%, and haematology 8.1% segments."

CZEDMA, Czech IVD industry association.

SWITZERLAND IVD MARKET 771 mEUR +49.9%

"After a negative growth (-3.7%) of the IVD market excluding SARS-COV-2 testing in 2020 vs 2019, we observed a recovery in 2021 with a growth of 6.5%. All Coronaviru testing experienced strong expected growth of almost 50% vs. 2020."

SVDI, Swiss IVD industry Association.

Data Gathering

The results presented above are based on individual 2021 estimates made for 27 countries, comprising of the EU countries, EFTA countries, the UK 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 <u>National Association Members</u> of MedTech Europe and the MedTech Europe's <u>Market Research Committee</u> have estimated the IVD market in 18 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, 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 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. Although most of the molecular tests for Coronavirus have been captured in the programmes as they are supplied by participating companies, there are revenues on Rapid Tests purchased directly through national government arrangements from non-participant companies which might not be all captured in this report.

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 driven by research and development. Almost 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

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