

European IVD Market Statistics Report 2021

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 **2020 and 2019 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. They play a vital role 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 unprecedented increase of + 25,4%. Overall revenues across EU-27, UK and EFTA reached **€13,971** million. When looking beyond the COVID-19 related diagnostics, there has been significant decline in tests in the other IVD segments such as clinical chemistry, immunology, microbiology, 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 Switzerland is the leading country at 13.2%, followed by France, Germany and Norway. In absolute amounts the healthcare expenditure per capita Switzerland remains in first position, followed by Austria, Luxemburg, Iceland, Germany, Belgium, Spain and France. The IVD per capita expenditure also shows a wide variation from a low of €5.1 in Bulgaria to €61.1 in Switzerland, which remains also the leading country.

IVD Market Statistics

Countries	Population 2020	GDP 2020	GDP / capita 2020	THE 2020	THE / capita	THE as % GDP	IVD mkt. 2020	IVD mkt. 2019	IVD mkt. growth rate 20-19	IVD mkt. / THE 2020	IVD mkt / capita 2020
	1000	Mio €	€	Mio €	€	%	Mio €	Mio €	%	%	€
	Source: Eurostat			Source: Fitch Solutions (provisional)			Source MedTech Europe				
Germany	83,167	3,367,560	40,492	428,640	5,154	12.7%	2,745	2,180	25.9%	0.6%	33.0
France ¹	67,320	2,302,860	34,208	294,703	4,378	12.8%	2,140	1,623	31.9%	0.7%	31.8
Italy	59,641	1,653,577	27,725	163,426	2,740	9.9%	1,776	1,558	14.0%	1.1%	29.8
Spain	47,333	1,121,948	23,703	115,405	2,438	10.3%	1,514	1,007	50.3%	1.3%	32.0
Netherlands	17,408	800,095	45,962	81,340	4,673	10.2%	365	286	27.6%	0.4%	21.0
Greece	10,719	165,326	15,424	16,216	1,513	9.8%	254	213	19.2%	1.6%	23.7
Portugal	10,296	200,088	19,434	20,325	1,974	10.2%	303	220	37.5%	1.5%	29.4
Belgium	11,522	456,893	39,652	51,130	4,437	11.2%	372	347	7.5%	0.7%	32.3
Sweden	10,328	475,432	46,035	54,557	5,283	11.5%	251	186	35.3%	0.5%	24.3
Austria	8,901	379,321	42,615	46,368	5,209	12.2%	465	288	61.5%	1.0%	52.2
Denmark	5,823	312,517	53,672	33,967	5,833	10.9%	176	161	9.5%	0.5%	30.2
Finland	5,525	236,032	42,718	23,805	4,308	10.1%	130	120	8.2%	0.5%	23.5
Ireland	4,964	372,869	75,108	25,296	5,095	6.8%	149	126	18.3%	0.6%	30.1
Luxembourg	626	64,221	102,572	N/A	N/A	N/A	21	19	10.5%	N/A	33.5
Poland	37,958	523,668	13,796	37,072	977	7.1%	454	377	20.6%	1.2%	12.0
Romania	19,329	218,863	11,323	10,244	530	4.7%	218	198	10.3%	2.1%	11.3
Czech Rep	10,694	215,257	20,129	16,784	1,569	7.8%	215	162	32.9%	1.3%	20.1
Hungary	9,770	136,622	13,985	9,416	964	6.9%	84	79	6.7%	0.9%	8.6
Bulgaria	6,951	61,331	8,823	4,805	691	7.8%	35	32	9.7%	0.7%	5.1
Slovakia	5,458	92,079	16,871	7,003	1,283	7.6%	97	78	25.2%	1.4%	17.8
Croatia	4,058	50,190	12,368	3,831	944	7.6%	67	65	3.5%	1.7%	16.4
Lithuania	2,794	49,507	17,719	3,312	1,185	6.7%	33	29	13.1%	1.0%	11.7
Latvia	1,908	29,511	15,470	2,372	1,243	8.0%	27	24	14.8%	1.2%	14.4
Slovenia	2,096	46,918	22,386	3,961	1,890	8.4%	62	54	16.0%	1.6%	29.8
Estonia	1,329	26,835	20,193	2,137	1,608	8.0%	26	21	21.7%	1.2%	19.7
Cyprus	888	21,548	24,266	N/A	N/A	N/A	10	10	10.0%	N/A	11.8
Malta	515	13,083	25,426	N/A	N/A	N/A	6	5	10.0%	N/A	10.7
EU27	447,320	13,394,150	29,943	N/A	N/A	N/A	11,995	9,464	26.7%	N/A	26.8
Switzerland	8,606	659,731	76,659	87,142	10,126	13.2%	526	462	13.8%	0.6%	61.1
Norway	5,368	318,051	59,254	38,762	7,222	12.2%	166	145	14.1%	0.4%	30.8
Iceland	364	19,025	52,248	N/A	N/A	N/A	12	11	10.0%	N/A	33.2
EFTA	14,338	996,807	69,523	N/A	N/A	N/A	704	618	13.8%	N/A	49.1
UK ²	67,026	2,425,151	36,182	267,745	3,995	11.0%	1,272	1,063	19.7%	0.5%	19.0
TOTAL (EU27, EFTA, UK)	528,683	16,816,108	31,808	N/A	N/A	N/A	13,971	11,145	25.4%	N/A	26.4
Turkey	83,155	626,576	7,535	30,537	367	4.9%	621	471	32%	2.0%	7.5
TOTAL (EU27, EFTA, UK, Turkey)	611,838	17,442,684	28,509	N/A	N/A	N/A	14,592	11,617	25.6%	N/A	23.8

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.

³ N/A - data not available in time of publishing.

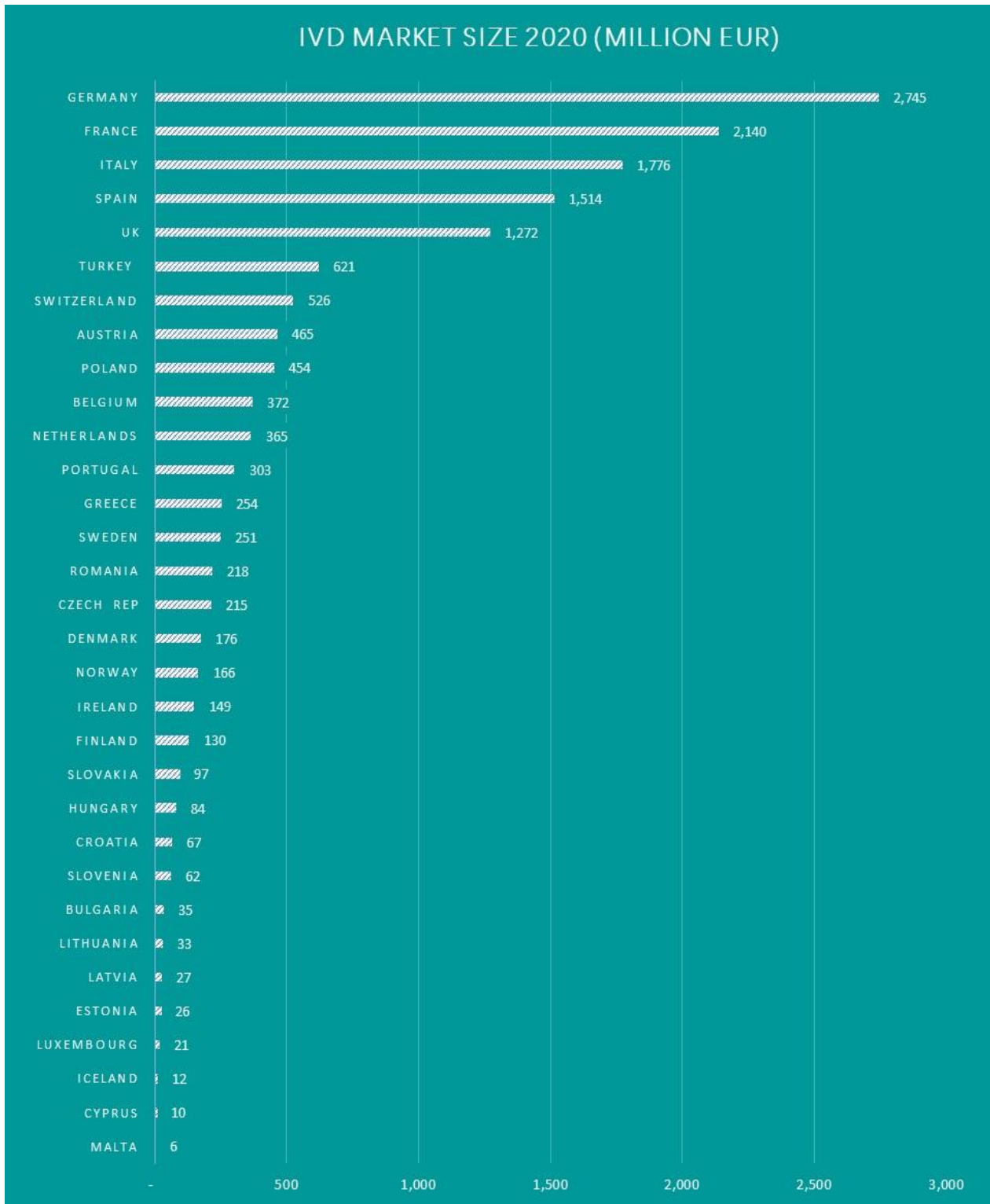
The applied exchange rates are the 2020 annual average exchange rates published by The European Central Bank. Applying a single exchange rate to both 2020 and 2019 sales data eliminates possible fluctuations of market size and market growth due to exchange variations. The impact of these fluctuations is shown in the table below.

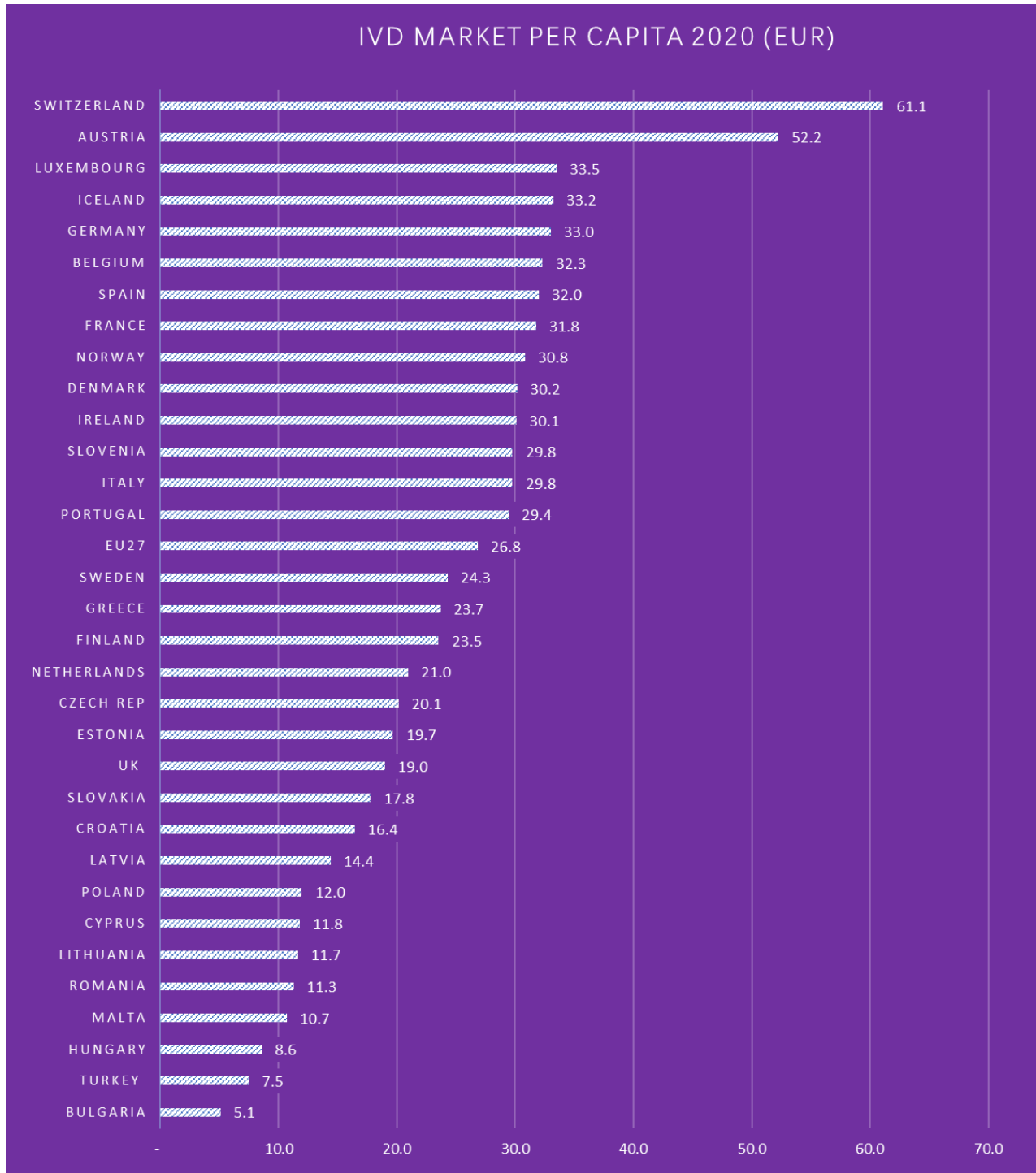
During the collection of 2020 year's figures, the 2019 market size was re-estimated at the same time. That, together with the use of a single exchange rate, explains why some countries show different revenues compared to the figures presented in last year's report for 2019. The growth rate between 2020 and 2019 has been calculated using the re-estimated figures. The 2020 data regarding population and GDP are the latest available from Eurostat. The figures regarding healthcare expenditure are the provisional 2020 data from Fitch Solutions.

IVD Market Size in EUR (using actual exchange rates)

Country	Currency	2020 Exchange Rate	2019 Exchange Rate	IVD mkt. 2020	IVD mkt. 2019	IVD mkt. 2020	IVD mkt. 2019	IVD mkt. growth rate 20-19
		Average	Average	Mio LC	Mio LC	Mio €	Mio €	%
Poland	PLN	0.2252	0.2327	2,015	1,678	454	390	16.2%
Romania	RON	0.2067	0.2107	1,054	956	218	201	8.2%
Czech Rep	CZK	0.03783	0.03896	5,690	4,282	215	167	29.0%
Hungary	HUF	0.002849	0.003075	29,106	26,739	83	82	0.9%
EU27	EUR			N/A	N/A	11,994	9,490	26.4%
UK	GBP	1.1248	1.1399	1131	945	1,272	1,077	18.1%
TOTAL (EU27, EFTA, UK)	EUR			N/A	N/A	13,970	11,186	24.9%
Turkey	TRL	0.12623	0.15747	4,918	3,735	621	588	5.6%
TOTAL (EU27, EFTA, UK, Turkey)	EUR			N/A	N/A	14,591	11,774	23.9%

Country Specific Data





SARS-Cov-2 Tests: Volumes 2020

Country	Total Tests	Tests per 1000 population
	Source: ECDC; *Our World in Data	
United Kingdom*	52,560,000	784
Germany	35,577,974	428
France	30,536,530	454
Italy	26,826,979	450
Turkey*	24,500,000	295
Spain	21,486,152	454
Denmark	10,576,739	1,816
Netherlands	8,149,414	468
Poland	7,886,328	208
Belgium	7,010,457	608
Portugal	6,058,651	588
Czechia	4,724,337	442
Sweden	4,641,125	449
Romania	4,567,152	236
Austria	3,747,074	421
Greece	3,432,711	320
Switzerland*	3,330,000	387
Norway	3,051,183	568
Luxembourg	2,751,987	4,395
Finland	2,510,908	454
Ireland	2,472,200	498
Hungary	2,412,823	247
Lithuania	1,577,134	564
Slovakia	1,436,746	263
Bulgaria	1,093,797	157
Croatia	1,084,453	267
Cyprus	939,253	1,058
Latvia	887,884	465
Slovenia	732,806	350
Estonia	550,119	414
Malta	527,375	1,025
Iceland	429,819	1,180

Germany +25.9% IVD MARKET 2,745 mEUR

“The German diagnostics market in 2020 recorded sales of EUR 2,745 million. This corresponds to growth of 25.9% compared to the previous year. The laboratory market (reagents and instruments) is growing by 20.8%. The rapid test market is growing by 37.9%.

The exceptional market development in the past year is due to the COVID-19 pandemic and the central importance of testing. The test manufacturers delivered what politicians and the market in Germany demanded. The infectious disease diagnostics market segment quadrupled in volume. Initially, growth was determined by nucleic acid-based corona diagnostics. In the fourth quarter, sales of SARS-CoV-2 rapid antigen tests exploded. This development explains the high growth of the overall rapid test market, which is normally dominated by declining sales in blood glucose self-monitoring. Another driver of the dynamic development of infectious disease diagnostics is molecular HPV testing, which has been part of the early detection of cervical carcinoma since January 2020. Infectious disease diagnostics accounted for around 32 percent of the total IVD market in Germany in 2020. In the previous year, the share was 10.3 percent. In contrast, there was a downward trend in all other segments. The sales declines are between two and sixteen percent. Restrictions in public life and a noticeable decline in the use of non-infectious health services are factors to be mentioned.” - [VDGH, German IVD industry association](#)

France +31.9% IVD MARKET 2,140 mEUR

“The Central Laboratory IVD French market (excluding diabetes) is estimated at 2,140 million Euro, with a growth of +31.9% compared to 2019. This huge increase is driven by SARS-CoV-2 IVD products. SIDIV has conducted a survey among its members showing that if SARS-CoV-2 IVD tests are excluded from the market figures, the trend is a diminution of -2,7%.” - [SIDIV, French IVD industry association](#)

Italy +14.0% IVD MARKET 1,776 mEUR

“The growth witnessed in the Italian market can be solely attributed to COVID-19 related diagnostics. Looking at the market data, excluding the COVID-19 diagnostics, Italy recorded an extremely negative figure of - 4.5%. The negative trend recorded in previous years has been greatly worsened because of citizens' difficulties in accessing outpatient services and the reduced activity of healthcare facilities as their focus was mainly on the management of the pandemic.

The above mentioned can be illustrated by the following market dynamics in the other IVD segments:

Clinical Chemistry (-11.30%);

Urine testing (-28.5%);

Glucose test strip (-11.20%);

Tumor Marker (-12.10%);

Auto-immune diseases (-11.60%).

What has been described regarding the year 2020, albeit to a lesser extent, is also observed in the first months of 2021. The lower number of specialists visits carried out in recent months is a sign of worsening the state of health of patients suffering from chronic diseases who have not undergone control tests since the beginning of the pandemic. “- [Confindustria Dispositivi Medici, Italian IVD industry association](#)

Spain +50.3% IVD MARKET 1,514 mEUR

“Due to pandemic situation the routine activity has declined a lot and in consequence the routine test declined steadily related with low follow up of chronic illnesses and surgical procedures. In the other side all COVID-19 related tests, considering not only the direct SARS-CoV-2 tests, but also other related with its evaluation, diagnosis and evolution had a huge increase. Companies manufacturing COVID-19 tests in Spain had been very successful selling their tests around the world. Molecular test performance has gotten a tremendous support and is expected to remain strong in the future. Self-test (diabetes) remains declining as previous years but POC mainly due to Covid Rapid tests grew strongly.

Laboratories have focused their activities to responded to the very high demand of covid related test changing structures and hiring personnel for the new areas and we have seen few progress in other fields of the laboratory medicine. There is a concern about future market evolution once the COVID-19 tests arrive to a peak and begin to decline. Future is uncertain and we expect to recover 100% of routine test, while and there is no certainty about COVID-19 related tests evolution.

IVD test are riding on the crest of the wave and citizens rely on this technology more than ever. We have to keep the momentum and seize the opportunity to reinforce the value of diagnostic information.” - [FENIN, Spanish IVD industry association](#)

United Kingdom +19.7% IVD MARKET 1,272 mEUR

“The headline UK IVD market size for 2020 is £1,131m with growth of almost 20% (£186m) over 2019. This exceptional annual growth is due to heavy investment in testing for Coronavirus plus additional testing required for COVID-19 positive patients in serious condition in hospitals. It is offset only partly by the cessation of elective treatments during the first national lockdown which started on the 23rd of March, and the slow recovery of normal clinical services subsequently. Although most of the molecular tests for Coronavirus have been captured in the survey as they are supplied by participating companies, there is a huge expenditure on Rapid Tests (Lateral Flow Tests, or LFTs) purchased directly through national government arrangements from non-participant companies which is not all captured in these figures. One of the largest is reported to have won a contract for at least £2.8billion for supply of LFTs for home testing, which is not captured in the audit.

The response to the pandemic was late but dramatic and included the establishment of dedicated 'Lighthouse laboratories' equipped purely for high volume PCR testing for COVID-19. Testing for other conditions and purposes dropped drastically. The impact on non-Covid revenues ranged from reductions of around 30% for drugs of abuse, allergy, and anemia, while Chlamydia testing was down over 80%. In contrast, some specific assays such as D-Dimer and Procalcitonin were greatly increased.” - [BIVDA, British IVD industry association](#)

Belgium +7.5% IVD MARKET 372 mEUR

“In 2020, because of COVID-19, there were less hospitalizations and consultations (i.e., in the first wave, 59% less hospitalizations and 43% less consultations) which resulted in less non-Coronavirus related IVD tests.” - [beMedTech, Belgian IVD industry association](#).

Portugal +37.5% IVD MARKET 303 M EUR

“In 2020, the Portuguese IVD market excluding COVID-19 tests decreased by 10.0% as consequence of the lockdown which led to a reduction in routine medical appointments.

Overall, the total IVD market increased 37.5% driven by COVID-19 tests, namely PCR and PoC-Rapid tests.

COVID-19 testing, despite being financially supported by NHS, has been performed in both segments – private and public setting. In this area, we also faced a changing competitive scenario, with entry of new competitors and a reinforcement of some existing ones.” - [APIFARMA, Portuguese IVD industry association](#)

Austria +61.5% IVD MARKET 465 mEUR

“The market development in Austria in 2020 with the extremely steep increase vs. 2019 is only due to the pandemic and the relevant testing (PCR, Antigen- and Antibody testing). The other segments clearly declined between -2% to -15% (depending on segment) due to fewer patient samples referred to the laboratories, fewer patients in out-patient hospital wards due to the lockdown restrictions and the clear focus of laboratories on COVID-testing. As a quite high number of new market players, who do not report their sales figures, entered with SARS-CoV-Testing methods the estimation of their sales might have a broad bandwidth.” – [AUSTROMED, Austrian IVD industry association](#)

Poland +20.6% IVD MARKET 454 mEUR

“In 2020, the market dynamic of +20.6% in Poland has been driven by COVID-19 tests, offsetting the decline in other segments. According to official sources, more than seven million SARS-Cov-2 tests have been performed in Poland. In comparison to 2019, we have observed decrease in the market of several groups of reagents (enzymes -5%, substrate -39%, electrolytes -8%), which is pointing out to decline or postponement in the medical services for patients. Further comparison of the market dynamics:

- Specific Proteins (-9%)
- Allergy (-22%)
- Tumour Markers (-11%)
- Thyroid Function Hormones (-16%)
- Fertility / Pregnancy Hormones / Proteins (-9%)
- Individual and Specified Hormones / Proteins +13%
- Anemia Related / Vitamin Tests (-7%)
- Therapeutic Drug Monitoring (-3%)
- Drugs of Abuse / Toxicology +4%
- Auto-Immune Diseases (-14%)
- Rheumatoid - Inflammatory Diseases Markers (-18%)
- Cardiac Markers 7%
- Immunohematology (Blood Grouping) 11%

The decline in some of the routine testing for patients that has been observed is worrying in regard to the health of the patients.” – [MedTech Polska, Polish IVD industry association.](#)

Greece +19.2% IVD MARKET 254 mEUR

“After three consecutive years of GDP growth (2017 +1.3%, 2018 +1.6%, 2019 +1.9%), a recession by 8.2% took place in 2020, due to the COVID-19 pandemic. In 2020, the total IVD Market grew by 19.2% compared to 2019, mainly driven by revenues of 50 million euro related to Coronavirus Testing. The Greek IVD Market, excluding Coronavirus Testing, declined by -4.2%. The pandemic brought about a single digit decrease in all traditional IVD categories (Clinical Chemistry, Haematology, Immunology excluding Coronavirus Testing, etc.).” – [SEIV, Greek IVD industry association](#).

Slovenia +16.0% IVD MARKET 62 mEUR

“In 2020, the estimated IVD market in Slovenia grew with 16%, due to the COVID-19 situation. The COVID-19 impact was calculated considering the number of SARS Cov2 tests performed in Slovenia in 2020 and the public tenders open for PCR instruments and RAT.

The COVID-19 strong measures had significantly slowed down the operationality of the Health Care System. Therefore, the core lab tests dropped by almost -20%, representing approximately 70% of the total market in 2020 only.

With the arrival of RAT (end of Q3 2020), the POC was growing by 70%. Most of the RAT tests were supplied by providers from Asia. The RAT had been seen as an exciting business opportunity. Therefore, many new IVD distributors (most not even in IVD before) have appeared on the market (e.g., in the RAT National tender in December 2020, more than 40 distributors were competing).

Diabetes care has not been considerably influenced by the COVID-19 measures and reported modest growth of +2,4%.” – [MedTech Slovenija, Slovenian IVD industry association](#).

Czech Republic +32.9% IVD MARKET 215 mEUR

“The significant market growth observed in 2020 in the Czech Republic has been driven by infectious disease testing +57.8%, due to the COVID-19 pandemic, as well as related increased revenues in genetic testing +34.7%, services +28,9% and instruments +3.4%.

Opposite market dynamic occurred in microbiology (-12.2), clinical chemistry (-10.2%), and hematology (-4.7%) segments.” – [CZEDMA, Czech IVD industry association](#).

Slovakia +25.2% IVD MARKET 97 mEUR

“The country market dynamics +25.2% growth observed in 2020 have been driven by the Coronavirus pandemic and the SARS-Cov-2 related tests.” – [SEDMA, Slovakian IVD industry association](#).

Switzerland +13.8% IVD MARKET 526 mEUR

“Excluding Coronavirus related testing, a negative growth (-3.7%) has been observed on the Swiss IVD market in 2020. The pandemic has negatively impacted the clinical chemistry segment with an annual growth of (-8.6%), as well as immunochemistry (-2.3%), and haematology / immunohematology (-1.6%) when compared to 2019.” -[SVDI, Swiss IVD industry Association](#).

Turkey +31.7% IVD MARKET 621 mEUR

“COVID-19 has led to an upsurge in some tests while causing a downward trend in others as COVID-19 related tests increased while testing for other diseases went down. Depreciation of Turkish Lira (+45%) and high inflation (+20%) increased the cost pressure on the import-driven industry. Suppliers and distributors could only partially implement price increases since tender durations are 1-3 years and prices cannot be increased during ongoing contracts.

Payment performance of all state and university hospitals kept worsening in 2020. In the second half of the year, the Ministry of Finance offered companies to write-off 25% of their receivables from all state and university hospitals (all invoices between January 1st, 2017 - September 1st, 2020) and receive the rest of the accumulated receivables within 3 months. The offer took the industry by surprise since such a request was made only for university hospitals before (twice, last time in 2018), which had chronic payment problems in the last 10 years and whose portion comprised only 30% of all accumulated company receivables. The previous rates had also been lower than 25% even though TL had depreciated 65% in the last three years. Companies’ response to the request had been mixed, but this move not only resulted in financial loss for the industry but also an erosion of trust for the country.

Opening of city hospitals financed by PPP model have continued. 13 hospitals have become active as of 2020 end, while the remaining 5 will be activated until the end of 2022. Meanwhile, 4 ISLAB tenders had been concluded for 4 regions covering all Istanbul and the winners had resumed their 3-year operations.” – [ARTED, Turkish IVD industry association](#).

DATA GATHERING

The results presented above are based on individual 2020 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 [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, 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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