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

In vitro diagnostics (IVDs) are an essential part of today’s healthcare. IVDs are used to diagnose, monitor, screen and assess predispositions to diseases, thereby contributing to the available medical information regarding a patient. By allowing earlier and more targeted treatments, IVDs help to reduce hospital stays and convalescences, resulting in healthier populations, reduced costs and economic growth in the long run.

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

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

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

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

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

During the collection of 2018 figures, the 2017 market size was re-estimated at the same time. That, together with the use of a single exchange rate to both 2017 and 2018 sales data eliminates possible market size and market growth fluctuations due to exchange variations. The impact of these fluctuations is shown in the table below.

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

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

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

Although there are variations in healthcare systems, reimbursement policies etc. from country to country, healthcare cost containment is constant across the various countries in this report. Besides budget restrictions, greater centralisation both in the public and private laboratory sectors has increased the power of purchasing organisations. The overall situation with days sales outstanding (DSO) in 2018 remains unsatisfactory.
In 2018, the Italian IVD market has slightly decreased by -0.2%. There are some reasons that help to explain such decrease. First, a co-payment system is still working and, even though some patient categories are excluded, other patients have to pay an amount up to €70.00 (only in some regions) for tests. Second, the drop of the glucose test market is another factor to explain the overall decrease. In fact, this market went down (-8.0%), and this figure influenced the IVD market. Generally, some segments of the IVD market increased compared to the previous year (mainly one of the smallest as the “genetic test”) while others decreased. It is important to stress that in 2019 many regions adopted a tighter cost containment strategies. On one hand the central government went on putting some limits to finance healthcare expenditure (and the ceiling limit of expenditure for devices is still 4.4% of the public healthcare expenditure). On the other hand, regions - that should have already received funds by pharmaceutical companies due to the pharma payback (excess expenditure on the pharmaceutical ceiling) did not receive such funds. “ - Confindustria Dispositivi Medici, Italian IVD industry association

In 2018, the Central Laboratory IVD French market is estimated at 1.614 billion €, with a growth of +0.8% compared to 2017. The Central Laboratory IVD French market has been in stagnation since 2015 with continuous non-significant growth of less than 1%.” - SIDIV, French IVD industry association

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

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

In 2018, the Polish IVD market showed a sales decline of 1.6% to 2.156 billion euros. This continues the downward trend of the previous year (-2.2%). The picture differed in the individual market segments. Sales for laboratory diagnostics (reagents and instruments) stagnated (-0.1%). In the rapid test market (+ R + I), sales fell by 4.8%. The laboratory market is suffering under the restrictive conditions for the remuneration of laboratory physicians. Almost all services are hedged. In clinical chemistry, there is also considerable price pressure. Slight growth can still be seen in microbiology and infectious immunology. A 6.1% decline in the market for blood glucose test strips dominates the entire rapid test market. However, this should be offset by significant growth in point-of-care (POC) analysis. POC market for reagents and instruments increased by +0.8% in Q1. “ - SIDIV, French IVD industry association

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"The IVD market in Spain continues with small growth. Mature test markets are declining due to price reductions and new test incorporation is not enough to get a clear positive trend. Aggregated purchasing and consolidation of laboratories is a trend but there is not too much room for consolidation. Most of the laboratories are already consolidated and looking for economy of scale and homogenization of the region’s procedures and technologies. Customers are looking for new contracts with lower price or value-based considerations but the implementation of these kinds of contracts is only testimonial. Costs increase for automation and digitalization in the context of a price driven market, especially in core labs. Introduction of innovative technology or new tests remains slow due to a very heterogeneous market with 17 autonomous regions with different technology incorporation processes and purchase approaches. There is no central process to incorporate new technologies. Market needs a tailor-made case integration processes and purchase agreements are therefore needed. " - FENIN, Spanish IVD industry association

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Portugal: +1.7% IVD MARKET 229 M EUR

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

Greece: +3.7% IVD MARKET 198 M EUR

"Following a multi-year economic crisis, the Greek economy is showing signs of recovery, with a 3% GDP increase from 2017 to 2018, in terms of Euro. It must also be noted that as of September 1st, 2019, capital controls are no longer in effect. The Greek IVD market grew in 2018, for third consecutive time after 2008 by 3.7%, reaching a size of €198M. 65% of the Greek IVD market comes from the public sector, while the remaining 35% comes from the private sector. The total public health spending in 2018 remained stable from 2017 at 5.1% of GDP. This number falls significantly behind the European average of 7.2%. Public procurement, based on tenders and negotiations, is dictated by the Observatory of Prices of the Ministry of Health, which continuously pushes prices down, regardless of technical specifications, volume or method. Under the current law, the criterion of lowest price is of higher importance than the criteria of quality and most advantageous economic offer in the majority of public tenders. In recent years, there have been several efforts to create the prerequisites for centralised procurement in the IVD sector, but without successful results so far. The private sector — accounting for approximately 35% of the total IVD market in Greece — is also under a lot of pressure and has contracted by more than 30% since 2009. Private healthcare providers (Private Labs) have been constantly suffering great losses annually, since 2013, in the form of clawback and rebates (reaching cumulatively even 60% in several cases) towards the main insurance provider, EOPYY. The suppliers and distributors could only partially reflect in prices since tender durations are 1-2 years and both depreciation and inflation accelerated in Q3 & Q4. Significant price pressure on the IVD industry and distributors continued; and the most prominent public institution has frequently requested price reductions. The same trend was seen in public tenders.” - SIEDEMA, Slovenian IVD industry association

Slovenia: +4.2% IVD MARKET 52 M EUR

"The IVD market has grown by +4.2% in 2018. The moderate growth momentum continued and had increased by +1% point versus last year. The growth was mainly due to the Laboratory market, +9.2%, with an outstanding contribution by Chemistry/Immunochrometry Instruments (+31.8%, most likely due to completion of some delayed tenders in 2018), and Infectious Immunology reagents + 25.5%. Overall Immunochrometry reagents kept the positive growth +9%, while a decline was registered in Clinical Chemistry reagents (- 0.8%) and more significantly in Haematology Reagents (- 15.3%). Diabetes market and POC markets stayed on the same level, with slight decreases; Diabetes (- 0.9%) and POC (- 1.8%). Significant price pressure on the IVD industry and distributors continued; and the most prominent public institution has frequently requested price reductions. The same trend was seen in public tenders.” - SIEDMA, Slovenian IVD industry association

Turkey: -2.4% IVD MARKET 645 M EUR

"End-user market value growth in local currency has reached double digits (+30%) not only because of the upsurge in number of tests (10%) but also due to the depreciation of the Turkish Lira (50%) and high inflation (20%), which the suppliers and distributors could only partially reflect in prices since tender durations are 1-3 years and both depreciation and inflation accelerated in Q3 & Q4 (more reflection of cost increases to prices are to be expected in 2019 & 2020). Payment performance of state hospitals worsened in 2018 both because SUT reimbursement points (partly determining the income of hospitals) remained the same and the fact that overall cost pressure on hospitals continued to surge with high level of inflation. On the positive side, university hospitals’ chronically accrued debts were paid to companies by the Ministry of Finance, albeit with discounts determined according to criteria based on age of debts (terms not accepted by all companies). The Budget deficit/GDP ratio increased to 2% by the end of 2018 due to increasing spending of public institutions; the upward trend is expected to continue within 2019, which might worsen the DSO’s of companies. The opening of city hospitals financed by PPP models have continued. Five hospitals have been launched in 2018, increasing the total number of PPP hospitals to nine. Current estimation for the completed number of hospitals in 2023 stands at 18, which is short of originally planned 30, due to funding issues. As a long-term initiative, The Department of Medical Diagnosis Services initiated two projects on rational medical screening and laboratory usage to maintain cost-effective/ sustainable test requests, which is expected to lead to volume reductions at laboratory and screening services from 2019 onwards.” - ARTED, Turkish IVD industry association
The results presented above are based on individual 2018 estimates made for 28 EU countries, the EFTA countries and Turkey:

- 14 countries participating in the Global Diagnostic Market Statistics (GDMS, former EDMS) programme: Austria, Belgium, Czechia, Denmark, France, Germany, Italy, the Netherlands, Poland, Portugal, Slovakia, Spain, Switzerland, and the UK.

- The National Association Members of MedTech Europe and the MedTech Europe’s Market Research Committee have estimated the IVD market in 18 other countries not participating in the GDMS programme: Bulgaria, Croatia, Cyprus, Estonia, Finland, Greece, Hungary, Iceland, Ireland, Latvia, Lithuania, Luxembourg, Malta, Norway, Romania, Slovenia, Sweden and Turkey.

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

More than 85% of the market is covered in major countries by GDMS, ensuring the reliability and objectiveness of the information provided by MedTech Europe and its members. MedTech Europe encourages all IVD suppliers and countries to participate in the GDMS programme, which is the largest In vitro diagnostic audit in Europe and the most accurate source of information for understanding and predicting market trends.
About In Vitro Diagnostics

In vitro diagnostics are non-invasive tests performed on biological samples (for example blood, urine or tissues) to diagnose or exclude a disease. IVDs provide valuable information about how the body is functioning and its state of health. They are used for diagnosis, prognosis, risk stratification, screening and therapeutic monitoring of diseases. IVDs have a broad scope ranging from sophisticated technologies performed in clinical laboratories to simple self-tests, such as those for pregnancy and glucose monitoring.

About MedTech Europe

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

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

For more information

Teodora Angelova
Market Data Manager
Email: t.angelova@medtecheurope.org
www.medtecheurope.org
Phone: +32 2 777 02 74