



# In Vitro Diagnostics (IVD) Market trends - *Overview*

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# Agenda

**Market size, segmentation and historical dynamics**

**Major market trends, inhibitors and key entry barriers**

**Competitive environment**





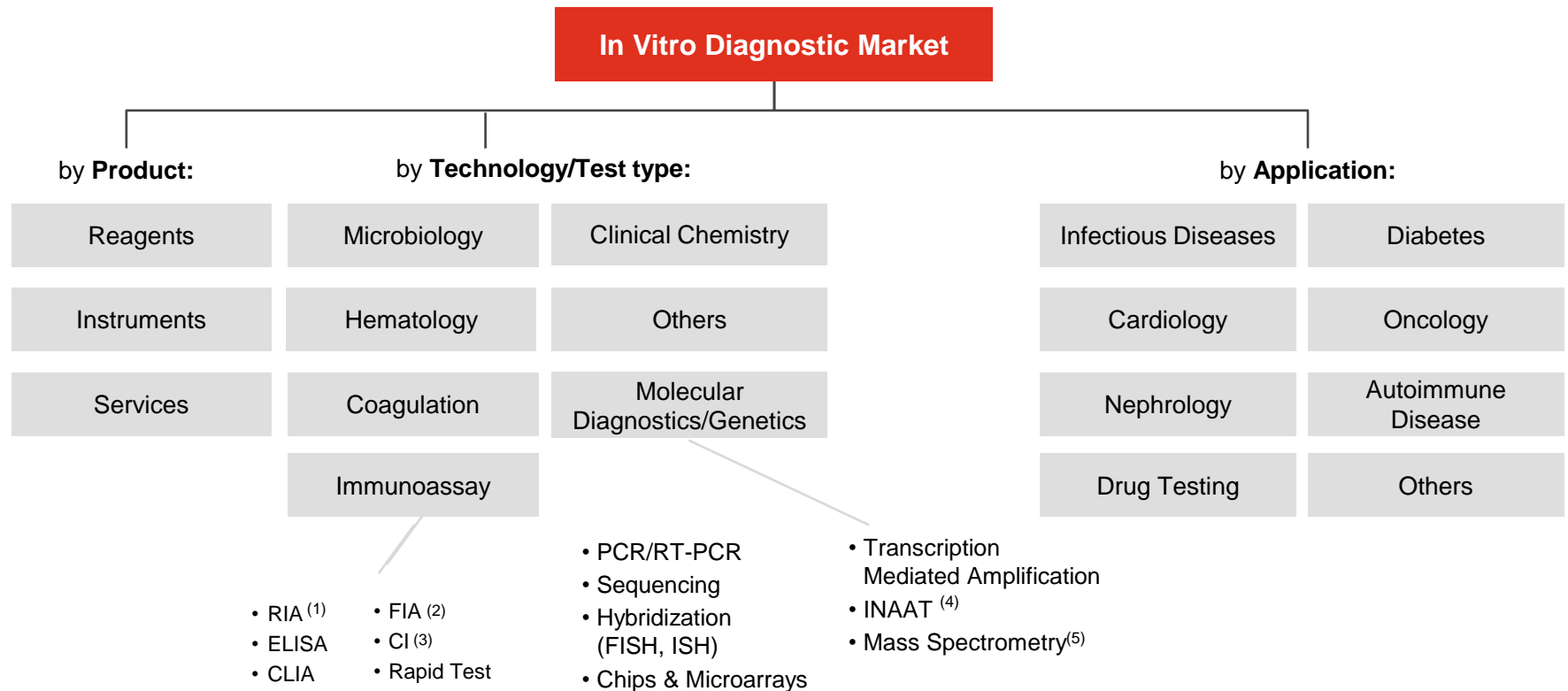
Market size, segmentation  
and historical dynamics

01



IVD tests are medical devices used to diagnose, monitor, screen and assess predispositions to diseases from assays in a test tube or in a controlled environment outside an organism, contributing to the available medical information of a patient.

## IVD market segmentation



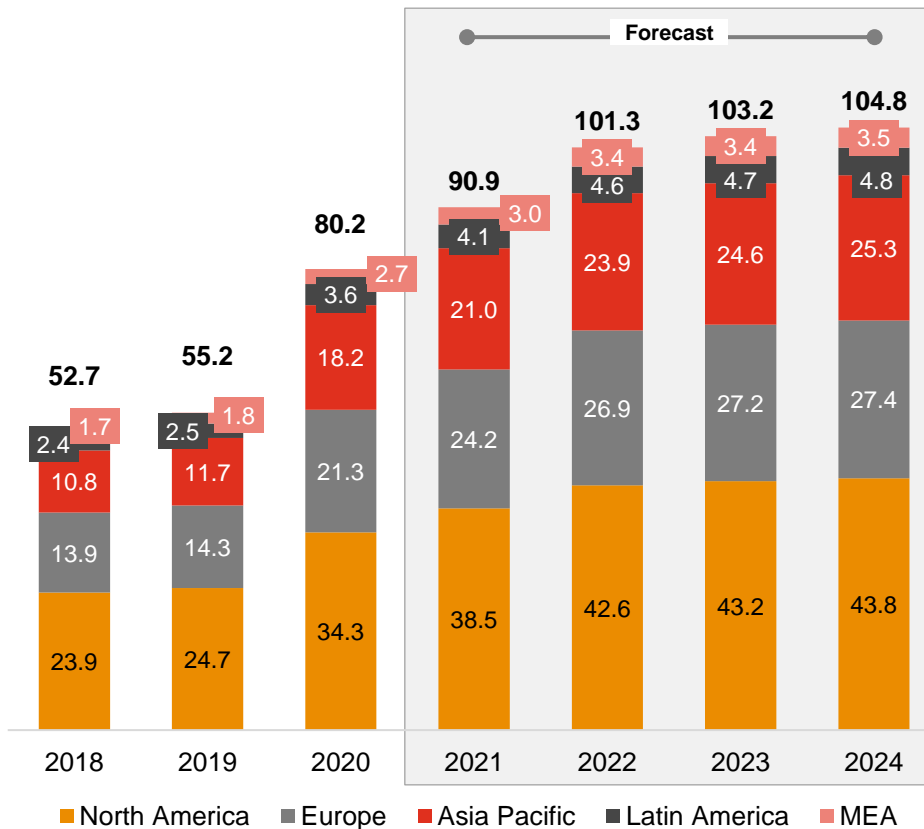
Sources: PwC Analysis

Notes: (1) RIA stands for Radioimmunoassay; (2) FIA stands for Fluorescence Immunoassay; (3) CI stands for Colorimetric Immunoassay; (4) Isothermal Nucleic Acid Amplification Technology; (5) Within the Molecular Diagnostics/Genetics segment, is adopted as accessory technology to perform specific analysis



The global IVD market is estimated ca. €80.2bn in 2020. North America is the main market and Asia Pacific the fastest growing. The market is being significantly and positively impacted by COVID-19 pandemic which led to a +45.4% YoY '19-'20 growth.

### Global IVD market by geography (2018-2024, €bn, %)



### Key Notes

YoY '18-'19	YoY '19-'20	CAGR '20-'24
+4.7%	+45.4%	+6.9%
7.4%	43.6%	7.1%
7.9%	43.6%	7.1%
8.5%	55.5%	8.6%
3.1%	48.8%	6.5%
3.4%	39.0%	6.2%

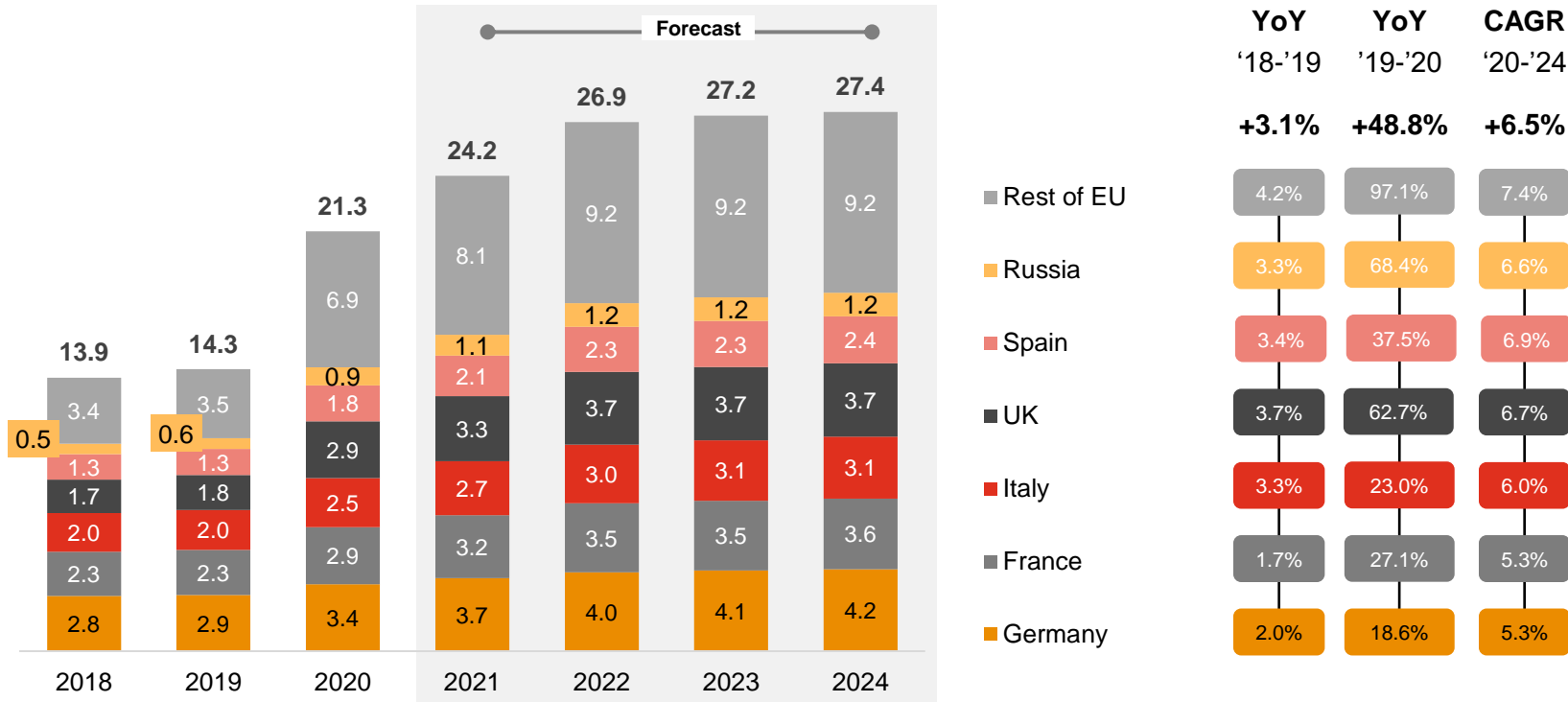
- COVID-19 pandemic is expected to continue to positively impact the market in 2021 and 2022, which is forecast to grow at a higher pace comparing to pre-pandemic levels (ca. 11%-13%) due to a progressive reduction of swab tests, but an increase in serological ones to map antibodies presence after vaccination
- As regards **technology segmentation**, Covid-19 has positively impacted **immunoassay** and **molecular diagnostics/genetics** with a +49.9% and 230.9% YoY '19-'20 growth respectively, while there has been a negative impact (ca. 3%-5%) on other segments due to decline in the number of installed bases and routine testing
- The same happened considering the **application segmentation** with **infectious diseases** recording a +166.2% YoY '19-'20 growth and others impacted negatively

Sources: PwC Analysis; Grand View Research  
 Notes: 2020 Average annual exchange rates from Banca d'Italia have been adopted: \$/€ = 0.877

The European IVD market is estimated ca. €21.3bn in 2020 and expected to grow at a +6.5% CAGR '20-'24. The largest market is Germany while smaller countries are expected to register the highest growth



European IVD market by geography (2018-2024, €bn, %)



Key Notes

- COVID-19 pandemic effect is in line with the one at a global level leading to a **48.8%** YoY '19-'20 growth driven by the molecular diagnostics/genetics and immunoassay segments
- The positive effect of Covid-19 on the European market is expected to persist up to 2022. After that, the growth curve is expected to flatten with a consolidation of the value reached even though Covid-19 tests will progressively disappear

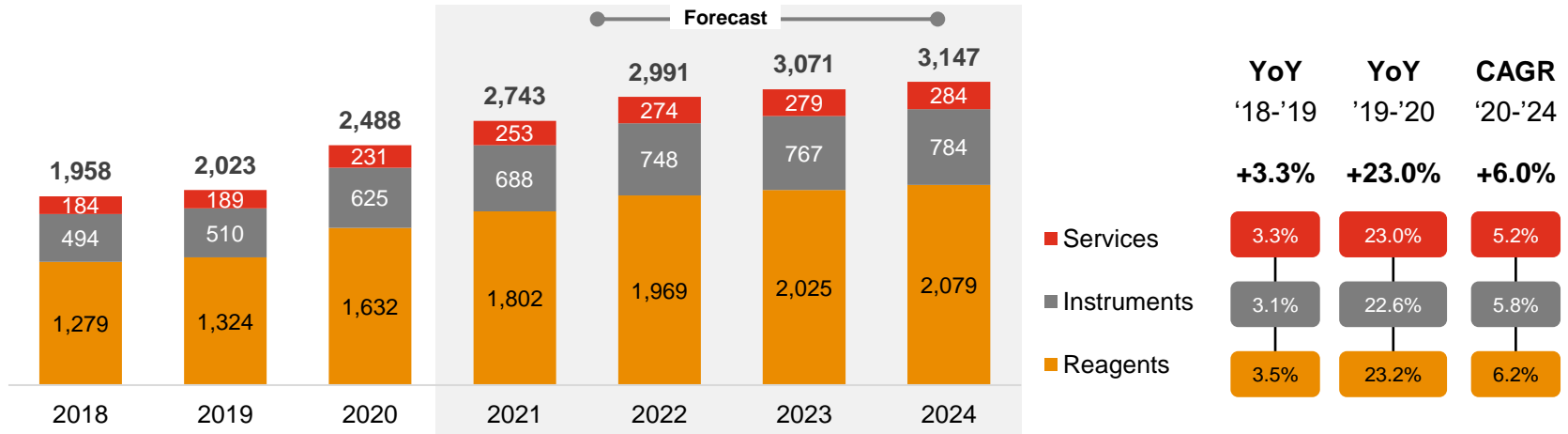
Sources: PwC Analysis; Grand View Research  
 Notes: 2020 Average annual exchange rates from Banca d'Italia have been adopted: \$/€ = 0.877



The Italian IVD market is estimated ca. €2.5bn in 2020 and expected to grow at a +6.0% CAGR '20-'24. Regarding type of product segmentation, reagents occupies the largest share (ca. 66%) and it is also the fastest growing.

By product

IVD market in Italy by type of product (2018-2024, €M, %)



Key Notes

- The D. Lgs 332/2000 defines as **IVD medical device** each medical device composed by a reagent, a reagent product, a calibrator, a control material, a kit, an instrument/device/system able to provide, through the analysis of a samples collected from the human body, information about the physiological/ pathological condition of a patient. The CE marking is necessary for the commercialisation of the device
- The Italian market is characterise by the presence of: (i) **italian subsidiaries of international companies** (mainly from the USA); (ii) **national producers**; (iii) **independent distributors**
- The **competition is high** especially on **routine tests** leading to low prices and reduced margins. Therefore the **market is mainly moving to specialised and esoteric tests**, services and innovative solutions
- The **clients' power is growing** mainly due to the laboratory consolidation trend
- The **main barriers to entry** the market are the technological know-how, economies of scale and capital requirements. Therefore the **main potential entrants** are either asiatic companies already leader in the IVD market or global leaders in adiacent markets through M&A activities

Sources: PwC Analysis; Grand View Research  
 Notes: 2020 Average annual exchange rates from Banca d'Italia have been adopted: \$/€ = 0.877

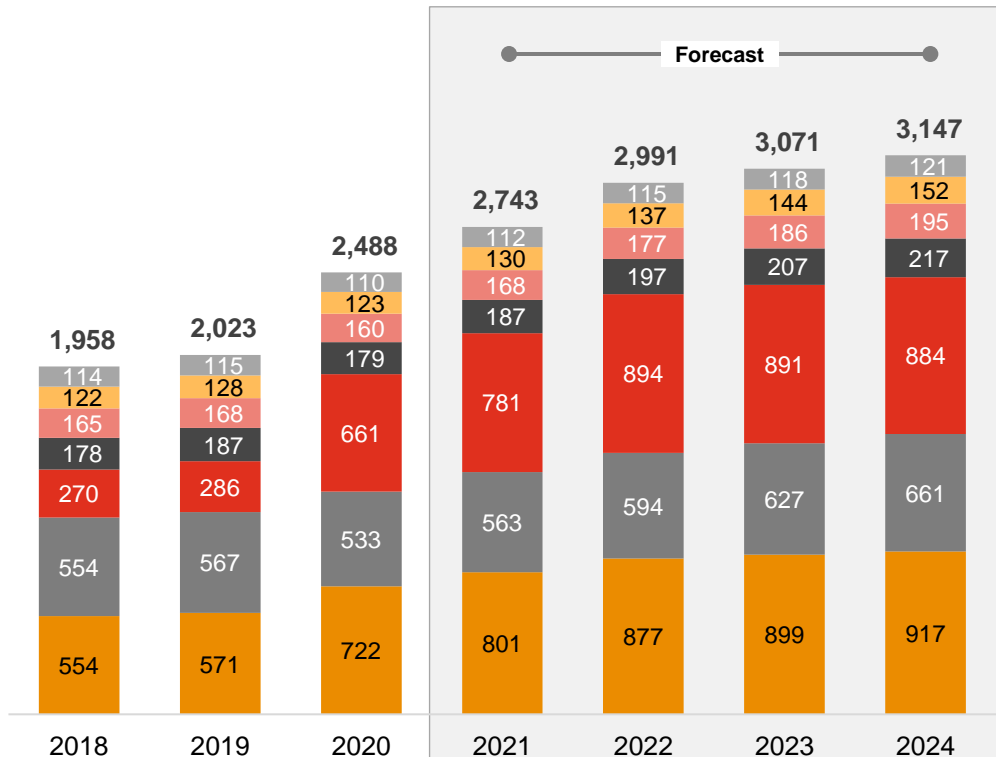


Looking at the segmentation by technology, Immunoassay is the largest segment ca. €722M in 2020, followed by molecular diagnostics (ca. €661M), the most enhanced by the advent of COVID-19 pandemic



**By technology**

**IVD market in Italy by technology (1/3) (2018-2024, €M, %)**



YoY '18-'19	YoY '19-'20	CAGR '20-'24
+3.3%	+23.0%	+6.0%
0.6%	(4.4)%	2.4%
5.2%	(3.9)%	5.3%
1.8%	(4.8)%	5.1%
5.0%	(4.5)%	5.0%
5.9%	130.7%	7.5%
2.3%	(5.9)%	5.5%
3.1%	26.3%	6.2%

**Key Notes**

- **Immunoassay** is a biochemical test measuring the presence/concentration of a macromolecule or a small molecule in a solution through the use of an antibody/ antigen
- **Molecular diagnostics/Genetics** aid in the assessment of a person's health at a molecular level through the detection and measurement of specific genetic signatures in deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) or the proteins they express

■ Immunoassay      ■ Clinical Chemistry      ■ Molecular Diagnostics /Genetics  
■ Hematology      ■ Microbiology      ■ Coagulation  
■ Others<sup>(1)</sup>

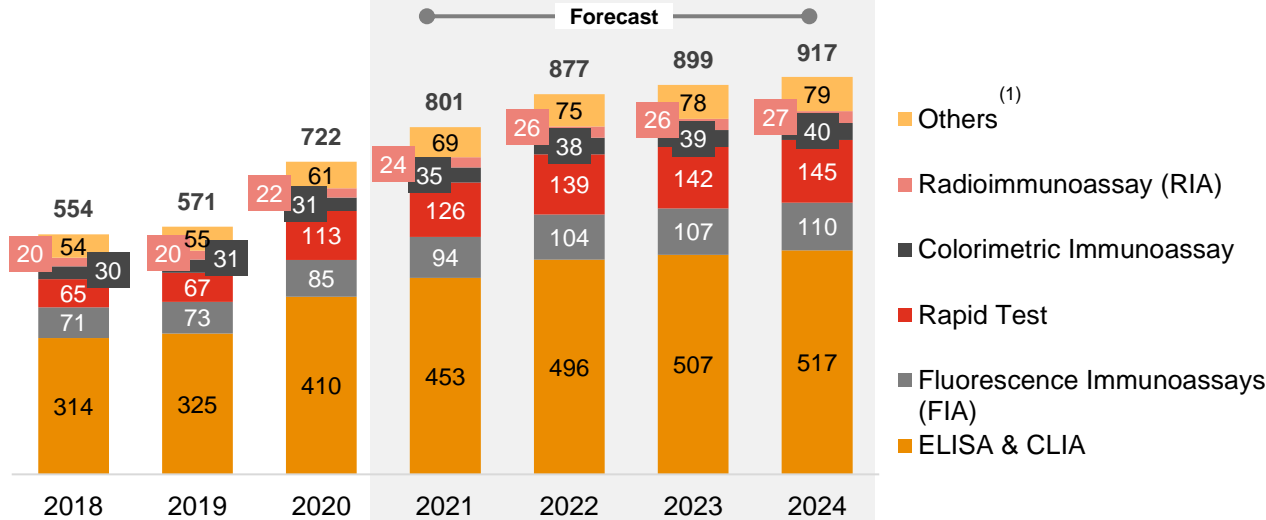
Sources: PwC Analysis; Grand View Research  
 Notes: 2020 Average annual exchange rates from Banca d'Italia have been adopted: \$/€ = 0.877; (1) Others include histology, flow cytometry analysis, urinalysis





# ELISA and CLIA techniques represent the most relevant subsegment in Immunoassay reaching €410M together in 2020, while the fastest growing subsegment is Rapid Test with +68.6% YoY growth '19-20' enhanced by COVID-19 spread

IVD market in Italy by technology (2/3) (2018-2024, €M, %)



## By technology

Technology	YoY '18-'19	YoY '19-'20	CAGR '20-'24
ELISA & CLIA	3.3%	26.2%	6.0%
FIA	3.2%	15.6%	6.6%
Rapid Test	3.0%	68.6%	6.5%
Colorimetric Immunoassay	3.0%	2.5%	6.0%
RIA	2.7%	6.3%	5.5%
Others	2.6%	10.5%	6.6%

### Key Notes

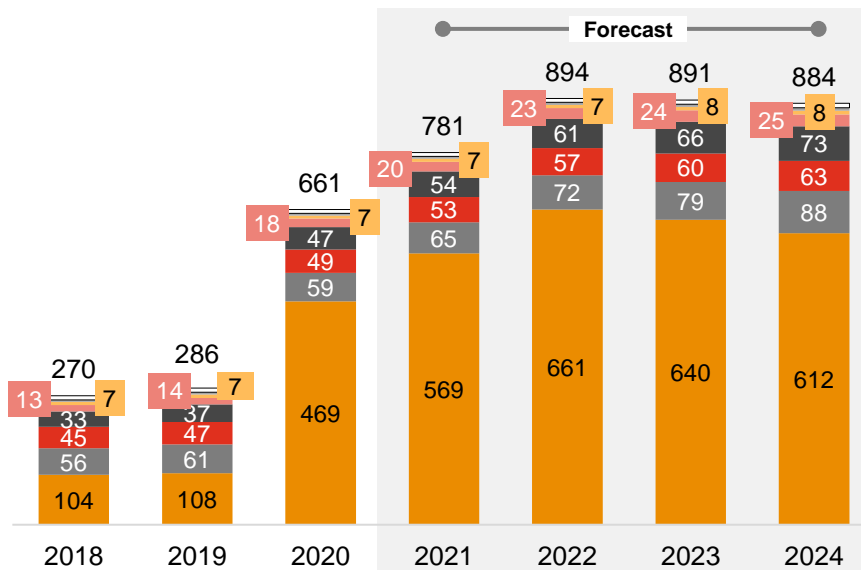
- Enzyme-linked Immunosorbent Assay (ELISA) detects antigens or antibodies by producing enzymes that trigger colour change in the substrate and it is considered the "standard" EIA test. **EIA (2) technique** is used to quantify peptides, proteins, antibodies, and hormones. EIA is preferred over radioimmunoassay as the latter use radiolabelled antibodies and antigens that can cause health problems. The growth of the EIA market is fuelled by expanding use of immunoassays in cancer, POC IVD, infectious disease testing and therapeutic drug level monitoring. The long shelf life and ease of use of these tests also contribute to the rise in acceptance in academic sectors.
- Chemiluminescence immunoassays (CLIAs)** are variations of standard ELISA tests. These assays use chemiluminescent molecules like luminol in substrate, which produces light when excited by chemical energy. The substrate does not require the addition of stopping reagents used in some colorimetric tests. Presently, CLIA offers one of the best solutions for quantification of low concentrations of samples from a complex mixture
- FIAs (3)** are variations of ELISA that use fluorescent labels to detect antigens and antibodies in a reaction. In these assays, fluorophores get attached to an antibody and the fluorescence is measured. Fluorophores are highly sensitive and relatively new immunoassay
- Rapid tests** are quick and easy to perform, being therefore suitable for preliminary or emergency medical screening especially in remote areas or where no sophisticated or advanced technology is available. They provide same day result usually within 30 minutes. They are becoming popular with COVID-19 pandemic and are expected to be increasingly adopted especially with POCT

Sources: PwC Analysis; Grand View Research; Notes: 2020 Average annual exchange rates from Banca d'Italia have been adopted: \$/€ = 0.877; (1) Others include western blot immunoassays and counting immunoassay; (2) EIA stands for Enzyme immunoassays; (3) FIAs are available in two formats, heterogeneous and homogeneous. Homogeneous are superior, as they do not require a separation step



The main subsegment of Molecular Diagnostics is PCR, which has been extensively adopted in COVID-19 detection tests, reaching €469M in 2020; Sequencing and Hybridization are the fastest growing ones with double digit '20-24' CAGR

### Molecular Diagnostics/Genetics in Italy by Technology (3/3) (2018-2024, €M, %)



- Others <sup>(1)</sup>
- Mass spectrometry <sup>(3)</sup>
- Chips and microarrays
- Isothermal Nucleic Acid Amplification Technology
- Sequencing
- Transcription Mediated Amplification
- In Situ Hybridization
- PCR <sup>(2)</sup>

### By technology

YoY '18-'19	YoY '19-'20	CAGR '20-'24
+5.9%	+130.7%	+7.5%
2.5%	(8.2)%	4.2%
4.0%	(6.4)%	6.0%
3.4%	(7.0)%	5.1%
7.5%	30.5%	9.0%
12.0%	27.3%	11.7%
4.3%	5.2%	6.2%
8.8%	(2.2)%	10.5%
3.5%	333.4%	6.9%

### Key Notes

- **PCR** (Polymerase chain reaction) is a method used to rapidly make millions to billions of copies of a specific DNA sample, allowing to take a small sample of DNA and amplify it to a large enough amount to study in detail. **RT-PCR** is based on a reverse transaction of RNA into DNA before amplification and it is used for RNA viruses such as Covid-19
- **Sequencing** is the molecular biology technique that determines the precise order of nucleotide bases (adenine, guanine, cytosine and thymine) in a given template of DNA. In general, sequencing allows HC practitioners to determine if a gene contains changes, called variants or mutations, that are linked to a disorder. **Next-generation sequencing** (NGS) is a massively parallel sequencing technology that offers ultra-high throughput, scalability, and speed. It has more multiplex capability than PCR, but it is more expensive and technically demanding
- **Microarray** main steps to detect specific patterns of molecules: (i) isolate and purify mRNA from samples of interest; (ii) reverse transcribe and label the mRNA; (iii) hybridize the labeled target to the microarray; (iv) scan the microarray and quantify the signal. The principle behind microarrays is that complementary sequences will bind to each other. Microarrays are being used to help diagnose diseases (e.g. cancer) and to develop treatments for them

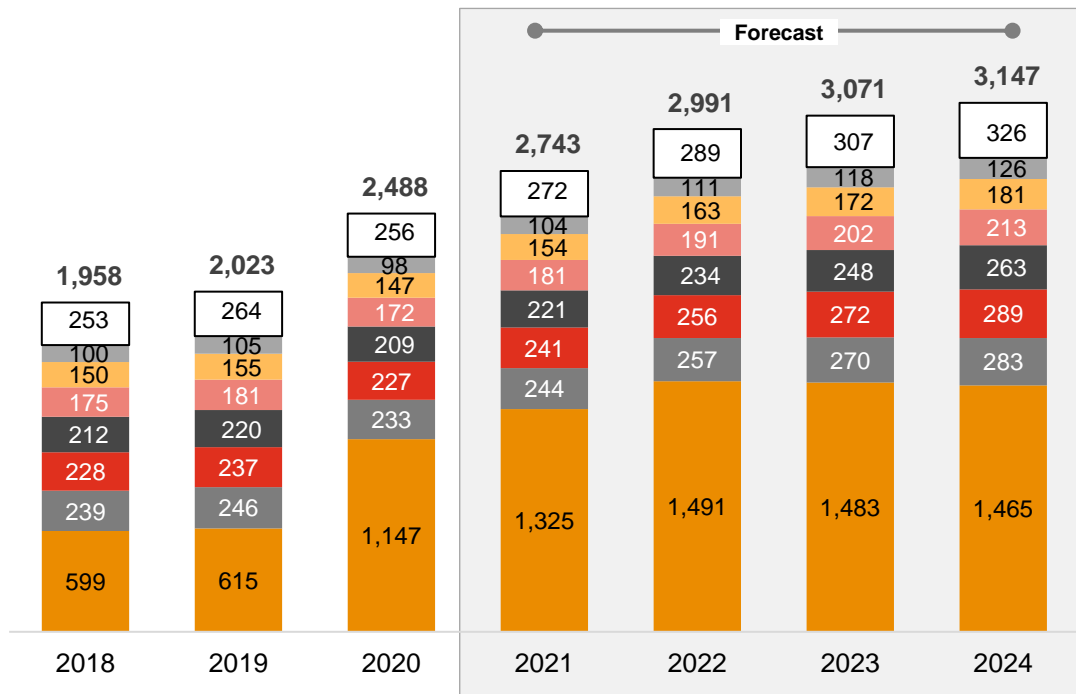
Sources: PwC Analysis; Grand View Research  
 Notes: 2020 Average annual exchange rates from Banca d'Italia have been adopted: \$/€ = 0.877; (1) Others include southern blotting, northern blotting, electrophoresis; (2) PCR includes also reverse transaction PCR and assembly PCR; (3) Within the Molecular Diagnostics/Genetics segment, is adopted as accessory technology to perform specific analysis



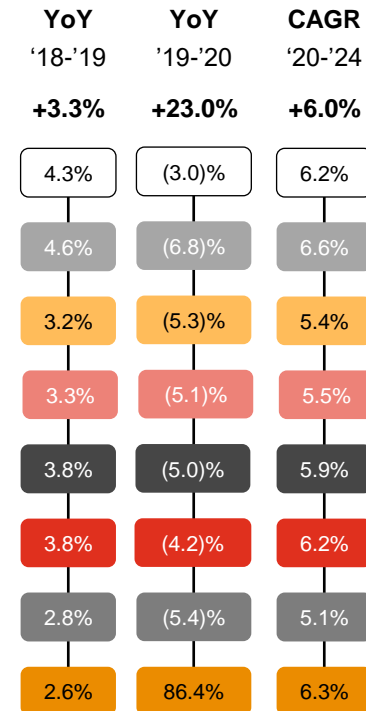
Regarding the market segmentation by application, Infectious diseases is the main segment and the only one to grow in 2020 with Covid-19 pandemic (+86.4% YoY '19-'20 growth) reaching ca. €1.1bn

By application

IVD market in Italy by Application (2018-2024, €M, %)



- Infectious Diseases
- Diabetes
- Cardiology
- Oncology
- Nephrology
- Autoimmune Diseases
- Drug Testing
- Other applications <sup>(1)</sup>



Sources: PwC Analysis; Grand View Research

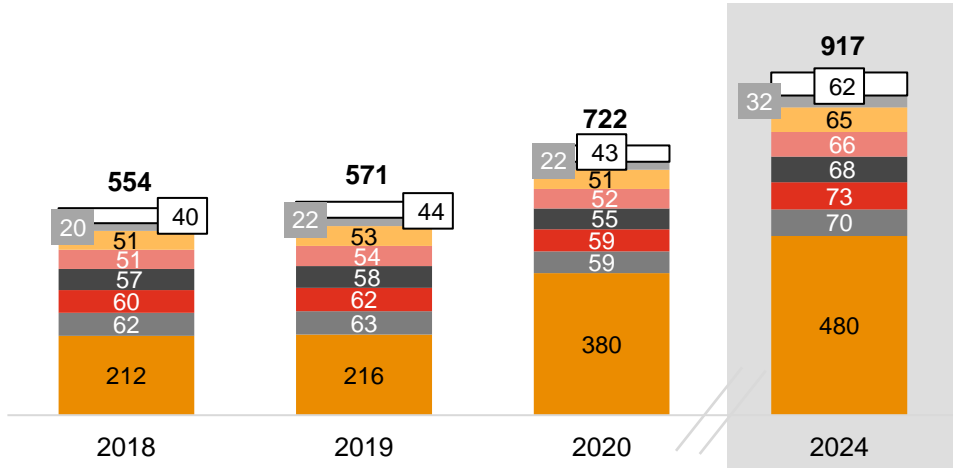
Notes: 2020 Average annual exchange rates from Banca d'Italia have been adopted: \$/€ = 0.877; (1) Others include pregnancy testing, blood gas & electrolytes testing, genetic testing, gastrointestinal diseases, endocrinology

# Technology-Application cross matrix



By application

## Immunoassay by Application (2018-2024, €M, %)

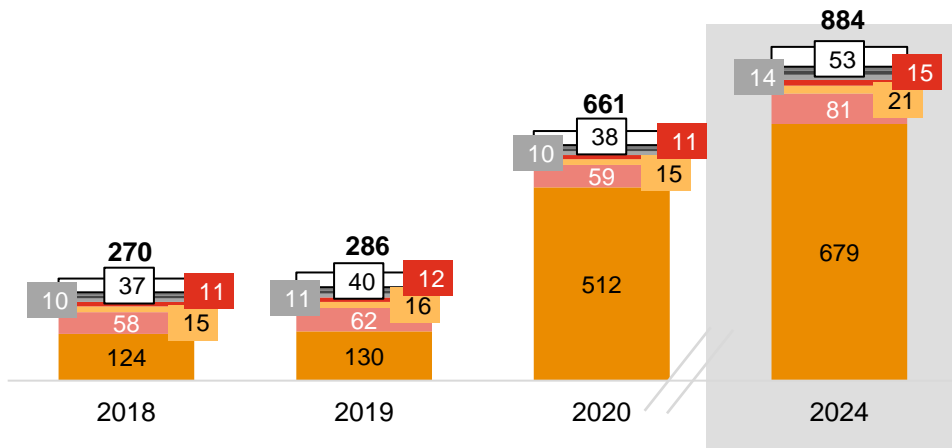


YoY	YoY	CAGR
'18-'19	'19-'20	'20-'24
+3.1%	+26.3%	+6.2%

1.6%	76.2%	6.0%
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- Other applications <sup>(1)</sup>
- Drug Testing
- Nephrology
- Oncology
- Diabetes
- Autoimmune Diseases
- Cardiology
- Infectious Diseases

## Molecular diagnostics/Genetics by Application (2018-2024, €M, %)



YoY	YoY	CAGR
'18-'19	'19-'20	'20-'24
+5.9%	+130.7%	+7.5%

5.5%	292.4%	7.3%
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Sources: PwC Analysis; Grand View Research

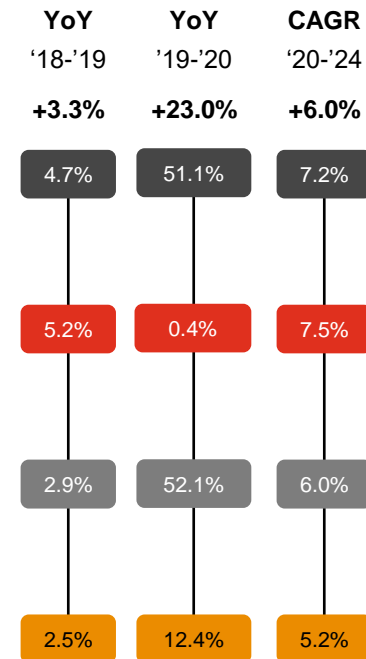
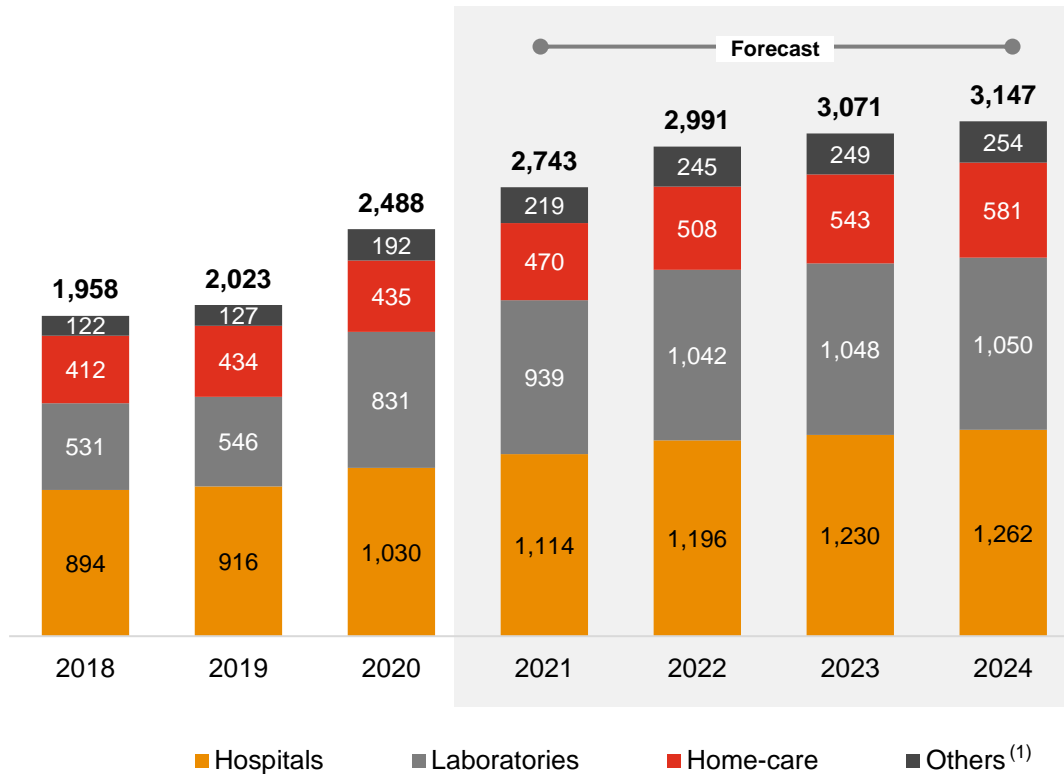
Notes: 2020 Average annual exchange rates from Banca d'Italia have been adopted: \$/€ = 0.877; (1) Others include pregnancy testing, blood gas & electrolytes testing, genetic testing, gastrointestinal diseases, endocrinology



Looking at the end-user market segmentation, laboratories have been the most active in the response to COVID-19 pandemic, while home-care and in general POCT<sup>(2)</sup>/delocalised healthcare is expected to have the fastest '20-'24 growth

By end-user

IVD market in Italy by End-user (2018-2024, €M, %)













Sources: PwC Analysis; Grand View Research

Notes: (1) Others include ambulatory care services, schools, academic institutions and research institutions; (2) Point-of-care testing (POCT) is a form of diagnostic testing in which the analysis is performed at or near the point of care, at the time and place where the patient is

# The IVD has been impacted by the COVID-19 outbreaks both in a positive and negative manner. The pandemic has forced companies in the industry to focalise their efforts to provide COVID-19 testing related products

Focus: COVID-19

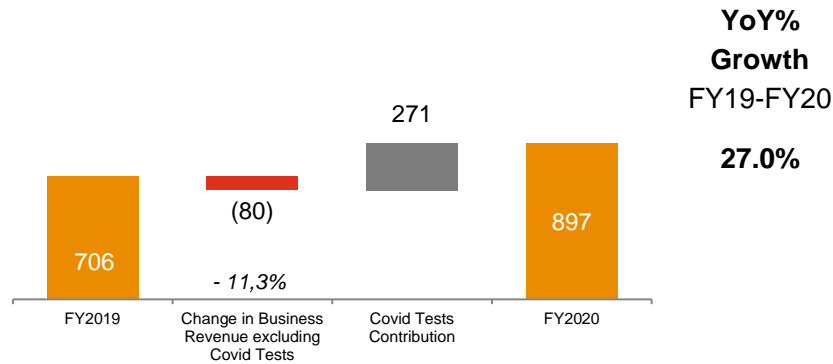
Key drivers	Description	Impact on IVD market
 <p>Lockdowns</p>	<ul style="list-style-type: none"> <li>Laboratories were open during <b>lockdowns</b>, and IVD testing for patients requiring emergency medical treatment have been performed, while the <b>regular/routine health examination tests</b> have been impacted in a negative way as these tests are not considered essential under medical emergencies. In addition, other factors which impacted the market in a negative manner include <b>restrictions related to functioning hours of laboratories</b> across the globe, which has been significantly decreased to prevent the spread of Covid-19. Furthermore, <b>closure of many departments of various hospitals</b> worldwide due to shortage of staff has also impacted the number of tests, which have been prescribed to non-Covid-19 patients</li> </ul>	 
 <p>Routine tests</p>	This cell is merged with the 'Lockdowns' row above	This cell is merged with the 'Lockdowns' row above
 <p>New COVID-19 tests</p>	<ul style="list-style-type: none"> <li>IVD testing has become a vital in <b>diagnosis of Covid-19</b>. This is evident by the large number of test kits launched for the detection of Covid-19 across the globe. These tests have been exempted from regular mandatory food and drug administration (FDA) approval and have been approved under an emergency use authorization (EUA) and are Conformité Européenne (CE). Some of the popular test kits for Covid-19 are <b>molecular diagnostic</b> test kits, <b>anti-body</b> test kits, and <b>antigen</b> test kits. Molecular diagnostic test kits use PCR-based testing and isothermal amplification methods for diagnosing the presence of virus/viral ribonucleic acid (RNA) in a sample. Molecular diagnostics is also expected to open avenues for effective disease prevention and early disease management by providing cost effective, accurate, and rapid diagnosis of diseases that have been difficult to analyse so far. Antibody test kits help in identifying people who have been previously infected with the virus. Antigen test kits use quick testing procedures that help identify the presence of active coronavirus infection in patients</li> </ul>	
 <p>Molecular diagnostics</p>	This cell is merged with the 'New COVID-19 tests' row above	
 <p>Rapid kits</p>	<ul style="list-style-type: none"> <li>Covid-19 outbreak has also diverted the focus of major market players toward the development of <b>rapid detection test kits</b>. For instance, the main IVD assay used for Covid-19 is based on real-time reverse transcriptase polymerase chain reaction (<b>RT-PCR</b>), which takes a few hours to detect the virus</li> </ul>	

Sources: PwC Analysis; Industry experts; Financial reports of major industry players; Allied Market Research; Bis Research; MedTech Europe; Mondor Intelligence; Technavio

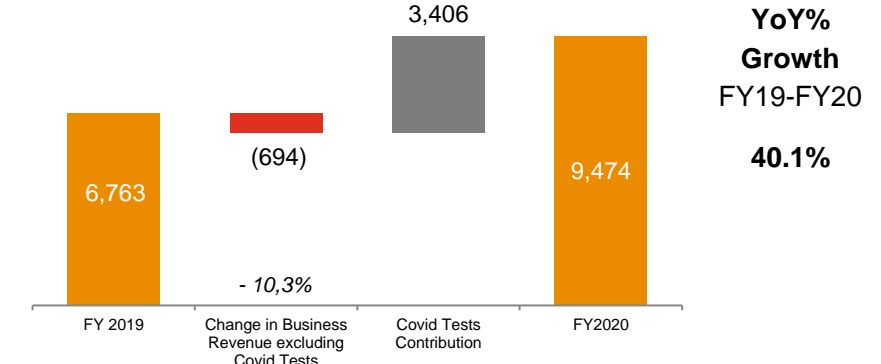
The overall impact of COVID-19 has been positive for the majority of the key players in the global in vitro diagnostics industry, with the new COVID-19 tests contribution offsetting the set-back on the rest of the business, mainly caused by lockdowns

Focus: Covid-19

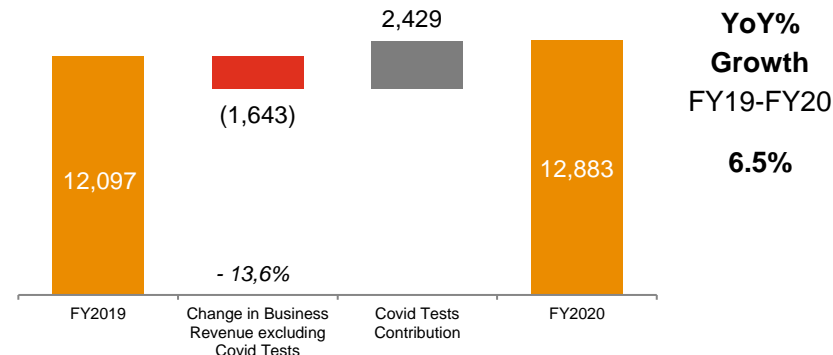
**Diasorin (FY19-FY20, Total Revenues, €M)**



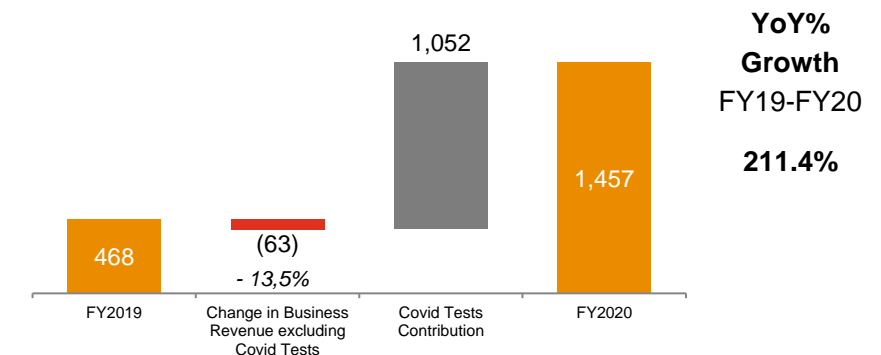
**Abbott (FY19-FY20, Diagnostic Segment Revenues, €M)**



**Roche (FY19-FY20, Diagnostic Segment Revenues, €M)**



**Quidel (FY19-FY20, Total Revenues, €M)**



Sources: PwC Analysis; Companies' financial statements and websites; Orbis  
 Notes: Quidel covid tests contribution obtained from annual report qualitative description

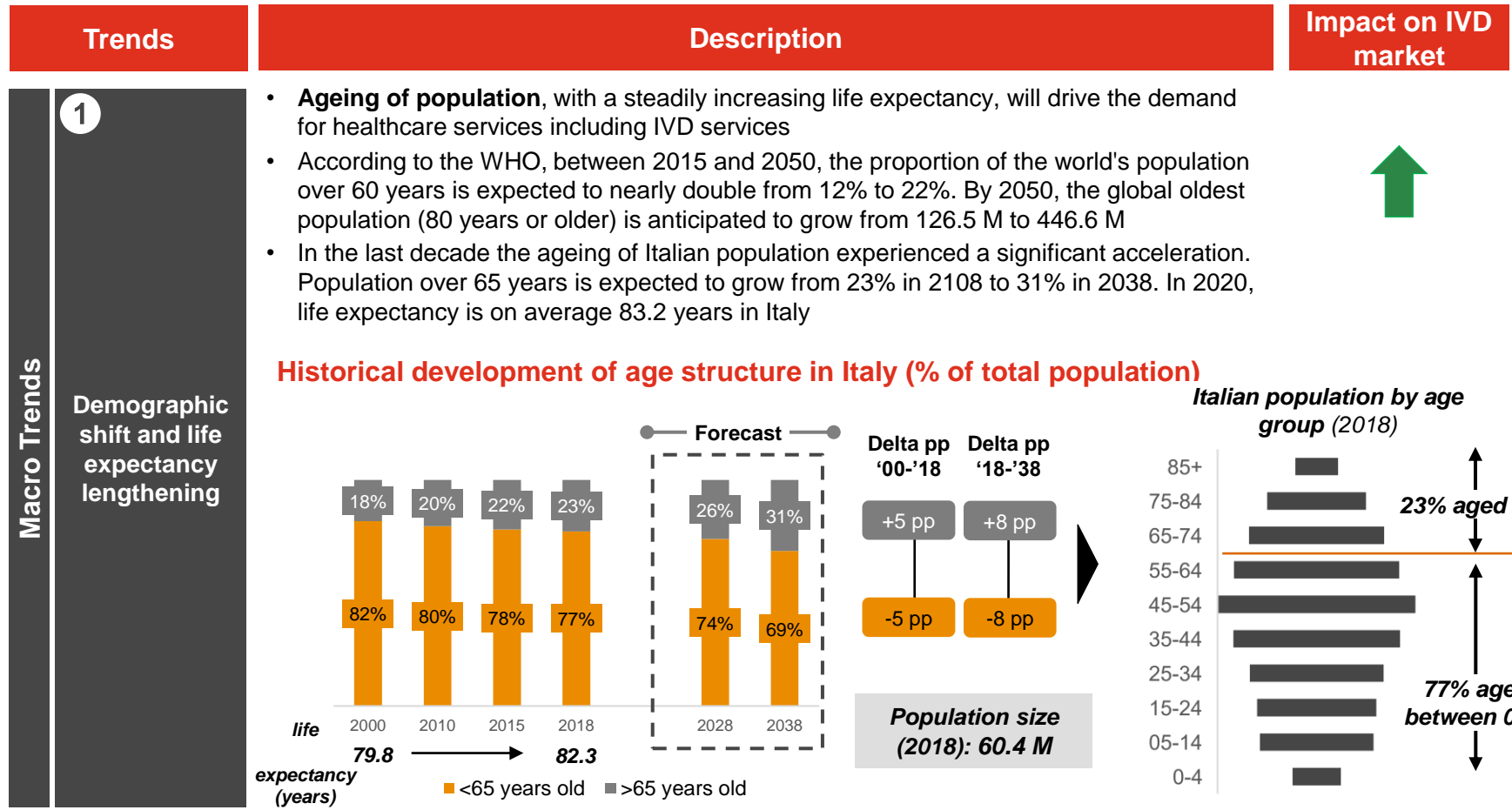




Major market trends, inhibitors and key entry barriers




02

There are macro, healthcare and specific IVD trends which are positively impacting the future growth of the In Vitro Diagnostic market.  
 Among macro trends: (i) Demographic shift and life expectancy lengthening ...



Sources: PwC Analysis; Industry experts; Financial reports of major industry players; Grand View Research, Allied Market Research; Bis Research; MedTech Europe; Mondor Intelligence; Technavio; WHO; OECD Health Data; ISTAT; Euromonitor; Confindustria Dispositivi Medici




Among healthcare trends: (ii) Increase in chronic and infectious disease; (iii) Increase popularity of personalise medicine and prevention; (iv) Healthcare spending growth and resiliency; ...

Trends	Description	Impact on IVD market
<p><b>2</b></p> <p>Increase in chronic and infectious disease</p>	<ul style="list-style-type: none"> <li>The burden of <b>infectious diseases</b> and <b>chronic disorders</b> is constantly growing worldwide. In Italy, almost half of the population aged 65+ has at least one chronic disease and 17% has two or more. Chronic disorders include different types of cancers, diabetes, cardiovascular disorders, obesity etc.. Infectious diseases are caused by microorganisms including diphtheria, ebola, flu, hepatitis, HIV/AIDS, human papillomavirus, tuberculosis etc. and outbreaks such as dengue, Zika virus, Swine flu and <b>Covid-19</b>, which is consistently impacting the growth of the infectious disease testing market segment</li> <li>The IVD market has great potential to obstruct the path of rising disease incidences by <b>early diagnosis</b> and <b>treatment monitoring/modification based on diagnostics</b></li> </ul>	
<p><b>3</b></p> <p>Increase popularity of personalised medicine and prevention</p>	<ul style="list-style-type: none"> <li><b>Development of epidemiology</b> and <b>increasing share of health-conscious people</b> is contributing to shifting the emphasis in <b>medicine from reaction to prevention</b></li> <li><b>Personalized medicine</b>, using an individual's genetic profile, helps in making decisions with regard to prevention, diagnosis and treatment of diseases. This results in identification of patients who are likely to benefit from a specific treatment, reducing unnecessary expenditure to those not likely to benefit from it. The cost of human genome sequencing has recently fallen, making the basis for personalized medicine widely affordable</li> </ul>	
<p><b>4</b></p> <p>Healthcare spending growth and resiliency</p>	<ul style="list-style-type: none"> <li>The <b>global</b> healthcare spending contributes to ca. 10% of the global GDP and is continuously rising in recent years due to the increasing health needs of the aging population, the growing prevalence of chronic and infectious diseases and the expansion of emerging markets</li> <li>The <b>IVD market</b> plays a significant role in the HC industry, <b>influencing over 60% of clinical decision making</b>. However, it <b>only accounts for ca. 2% of total HC spending</b>, signifying an enormous potential for cost-effective tests</li> <li>The <b>HC spending has proven resiliency</b> to periods of economic downturn ensuring stability for the in vitro diagnostic products and services. In <b>Italy</b>, public HC continues to grow during economic crisis and private HC spending decreases less than GDP during a downturn and tends to increase more during positive cycles</li> </ul>	

Sources: PwC Analysis; Industry experts; Financial reports of major industry players; Grand View Research, Allied Market Research; Bis Research; MedTech Europe; Mondor Intelligence; Technavio; WHO; OECD Health Data; ISTAT; Euromonitor; Confindustria Dispositivi Medici

## (v) Government support and EU funds.



Among specific In Vitro Diagnostic trends: (vi) Increasing adoption of rapid diagnostic; (vii) Rise in the demand for POC testing; ...

Trends	Description	Impact on IVD market
<p><b>5</b></p> <p>Healthcare Trends</p> <p>Government support and EU funds</p>	<ul style="list-style-type: none"> <li>Government support is an important growth factor for IVD market in the near future, since increasing funding by the government helps the research institutes to develop prompt analyser systems useful for the diagnosis of various diseases through a range of samples</li> <li>In Italy, the <b>Recovery Plan</b> (Next Generation EU) has an overall value of €235.6 bn to be adopted within 2026. <b>Mission 6</b> of the plan presented by Mario Draghi regards <b>Healthcare</b>. It amounts to ca. <b>€20.3 bn</b> of which ca. €9bn to develop and <b>enhance the local healthcare structure and telemedicine</b>, while €11.3bn to support <b>innovation</b> and <b>research</b> and the <b>digitalisation of the SSN</b></li> </ul>	 <p>COVID-19</p>
<p><b>6</b></p> <p>Specific IVD Trends</p> <p>Increasing adoption of rapid diagnostic</p>	<ul style="list-style-type: none"> <li>The increase in HC costs related to the ageing of population, the increase in chronic and infectious disease and especially the <b>Covid-19</b> pandemic spread created the need for <b>faster, accurate, informative, more affordable, and less invasive diagnostic tests</b> (e.g. antigen COVID-19 swab, rapid Covid-19 serological test to detect IgM/IgG antibodies)</li> </ul>	 <p>COVID-19</p>
<p><b>7</b></p> <p>Specific IVD Trends</p> <p>Rise in the demand for Point of Care Testing (POCT)</p>	<ul style="list-style-type: none"> <li>In the past, IVD technologies were used only in clinical labs. A majority of clinical chemistry, immunochemistry and haematology testing are still performed using high throughput instrumentation with complex automation. However, Point of Care Testing is growing in order to satisfy the need for <b>rapid identification</b> of both chronic and infectious diseases close to <b>where the patients are located</b></li> <li><b>key players</b> are <b>focused on launching fast, small, transportable, portable and simple to handle instruments</b> which can be easily used outside laboratory settings</li> <li>COVID-19 outbreak has underline the <b>necessity of strengthening local medical care</b> especially in Italy. This need is expected to enhance the <b>delocalisation of the diagnostic offer</b> including <b>auto-diagnostic</b> and <b>home-diagnostic</b></li> </ul>	 <p>COVID-19</p>

Sources: PwC Analysis; Industry experts; Financial reports of major industry players; Grand View Research, Allied Market Research; Bis Research; MedTech Europe; Mondor Intelligence; Technavio; WHO; OECD Health Data; ISTAT; Euromonitor; Confindustria Dispositivi Medici

COVID-19 Impact boosted by COVID-19 pandemic

# (viii) Labs consolidation in Italy; (ix) Leasing of IVD equipment; (x) Innovation and technological advancements





Trends	Description	Impact on IVD market
<p>8</p> <p>Labs consolidation in Italy</p>	<ul style="list-style-type: none"> <li>• <b>Decreasing tariffs vs. high fixed / variable costs</b> and <b>minimum number of services</b> to be performed to <b>maintain accreditation</b> threaten smaller laboratories. Significant <b>market fragmentation</b>, increased complexity, <b>budget cuts</b> and <b>stricter quality standards</b> are driving labs consolidation</li> <li>• The <b>current post-COVID-19 environment</b> is expected to drive further labs consolidation due to difficulties encountered by small players</li> <li>• Lab consolidation is an <b>opportunity for major players in the IVD market</b> to sell additional complex automation platforms to large laboratory hubs, while it is a <b>threat for those operating in smaller segments/niches</b>, indeed small labs are either closing or transforming into collection points</li> </ul>	 <p>COVID-19</p>
<p>9</p> <p>Leasing of IVD equipment</p>	<ul style="list-style-type: none"> <li>• Due to the <b>high cost of the IVD equipment</b>, manufacturers tend to <b>lease</b> equipment to end users, along with the contract to purchase associated reagents or assays for the equipment over the life of the contract by the same manufacturer. This might be fruitful for manufacturers as well as end users, as the former generates up to 75% of their sales from consumables, and the latter can use expensive equipment with no upfront cost</li> </ul>	<p>=</p>
<p>10</p> <p>Innovation and technological advancements</p>	<ul style="list-style-type: none"> <li>• The lack of man power in managing large laboratories that are involved in processing different tests can be addressed by automating laboratory functions leading to a <b>growing adoption of automated platforms</b></li> <li>• It is expected an increase in <b>specific and specialised tests</b>, prescribed gradually. The already large number of available tests will continue to grow to close indication gaps</li> <li>• <b>Product solutions</b> will be <b>designed to be as much integrated as possible with the workflow</b> to increase efficiency and effectiveness</li> <li>• <b>Real time clinical diagnostic devices</b> such as the prototype microfluidic device called 'Real-time ELISA developed by Stanford University (Jan 2021) are expected to revolutionize disease diagnosis</li> </ul>	 <p>COVID-19</p>

Sources: PwC Analysis; Industry experts; Financial reports of major industry players; Grand View Research, Allied Market Research; Bis Research; MedTech Europe; Mondor Intelligence; Technavio; WHO; OECD Health Data; ISTAT; Euromonitor; Confindustria Dispositivi Medici

COVID-19 Impact boosted by COVID-19 pandemic



# Uncertain regulatory environment, possible shortage of raw materials, purchasing centralization and restrictive regulations on medical devices and tests are among the main challenges for the IVD market

Inhibitors	Description	Impact on IVD market
<p>1</p> <p>Uncertain regulatory environment</p>	<ul style="list-style-type: none"> <li>In the EU, Directive 98/79/EC of the European Commission provides regulatory guidelines for the manufacturing and commercialization of in-vitro diagnostics devices in Europe. The <b>time frame required for receiving regulatory approval for some IVD is uncertain</b>, and investments made in R&amp;D may go in vain if the regulatory authority denies approval</li> <li>A <b>new directive</b> is expected to be introduced <b>next year</b> reducing the IVD products in auto-certification. This <b>will increase</b> approvals <b>uncertainty</b> and stretch out the time to obtain them. The only products that are expected to remain in auto-certification are instruments/machines.</li> </ul>	
<p>2</p> <p>Shortage and variable cost of raw materials</p>	<ul style="list-style-type: none"> <li>The marginality of an IVD kit depends on the cost of the relative raw materials. Both an eventual <b>price increase of raw materials</b> and an eventual <b>shortage</b> of them would generate a block in the value chain</li> <li><b>Lack of reagents</b> was a relevant issue in the first phase of the <b>COVID-19</b> outbreak, greatly reducing the test capability on the European population. Lack of RNA- extraction kits was the bottleneck to higher manufacturing capacity for Covid-19 molecular-assay tests</li> </ul>	
<p>3</p> <p>Purchasing centralization and payback on medical devices</p>	<ul style="list-style-type: none"> <li>In Italy, <b>public tenders</b> are becoming <b>more and more centralised</b> with interregional and regional tenders that have become customary</li> <li>As regards medical devices, the Italian regulation is considering to require progressive contribution (<b>payback</b>) to be paid by the medical devices companies to the SSN in order reduce the potential regional budget overrun</li> </ul>	
<p>4</p> <p>Criterion of appropriateness in Italy</p>	<ul style="list-style-type: none"> <li>From January 2016 with the application of <b>D.M. Lorenzin</b>, it has started a more selected prescription of diagnostic tests on a national basis in order perform only the necessary tests and reduce waste</li> </ul>	

Sources: PwC Analysis; Industry experts; Financial reports of major industry players; Grand View Research, Allied Market Research; Bis Research; MedTech Europe; Mondor Intelligence; Technavio; WHO; OECD Health Data; ISTAT; Euromonitor; Confindustria Dispositivi Medici

COVID-19 Impact boosted by COVID-19 pandemic

# Government cost savings, overall decreasing tariffs and restrictions and delays on reimbursements are other relevant limitation to the IVD market

Inhibitors	Description	Impact on IVD market																					
<p>5</p> <p>Demographic shift and life expectancy lengthening</p>	<ul style="list-style-type: none"> <li>The <b>Italian government</b> has adopted a <b>cost savings policy</b> in the last years continuously reducing the budget intended to the healthcare sector depleting the SSN and leading to the <b>downward homogenization of the tariffs</b> paid by the local health authorities and private clients</li> <li>In several European countries <b>reimbursement regimes have been tightened</b>. The limitations are profound especially for novel diagnostics developers whose coverage evaluation process lacks transparency and varies across payers. Novel diagnostic developers do not have a clear set of expectations for the level of evidence that is necessary for reimbursement. This has created <b>inefficiencies in the development of novel diagnostics</b> and a relevant increase in unnecessary R&amp;D costs</li> <li><b>Late payment for diagnostics products and services</b> has been a cause of concern in some parts of Western Europe. This has been a major problem, especially in Italy, where health structures, accumulating late payments, increase the overdraft that the regions owe to companies in the sector. The Italian national average of sales outstanding related to medical devices has been five times more than the EU recommendation of 60 days (2011/7/UE). However the <b>Italian situation has improved</b> in the last few years as show below:</li> </ul> <p><b>Medical device suppliers average DSO in Italy <sup>(2)</sup> (1995-2020, # days)</b></p> <table border="1"> <caption>Medical device suppliers average DSO in Italy (1995-2020, # days)</caption> <thead> <tr> <th>Year</th> <th>Max DSO</th> <th>Min DSO</th> </tr> </thead> <tbody> <tr> <td>1995</td> <td>359</td> <td>313</td> </tr> <tr> <td>2000</td> <td>290</td> <td>282</td> </tr> <tr> <td>2005</td> <td>337</td> <td>305</td> </tr> <tr> <td>2010</td> <td>297</td> <td>273</td> </tr> <tr> <td>2015</td> <td>176</td> <td>156</td> </tr> <tr> <td>2020</td> <td>108</td> <td>98</td> </tr> </tbody> </table> <p><b>Italian national medical device overdraft €1.7bn <sup>(1)</sup></b></p>	Year	Max DSO	Min DSO	1995	359	313	2000	290	282	2005	337	305	2010	297	273	2015	176	156	2020	108	98	<p>↓</p> <p>↑</p>
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 Notes: (1) as of March 2021; (2) Data analysed on a monthly basis



There are five significant barriers to enter the IVD market: i) high capital requirement, ii) regulations, iii) economies of scale, iv) know how and v) sales & distribution network

### Key barriers to access the IVD Market

<p><b>High capital requirement</b></p>	<ul style="list-style-type: none"> <li>• High start-up investment costs</li> <li>• High switching costs for customers that purchase bespoke solutions from existing players</li> <li>• Costly IVDR certifications processes</li> <li>• High investments in R&amp;D or M&amp;A strategies in order to innovate and to diversify the product portfolio in order to maintain competitiveness</li> </ul>
<p><b>Regulation / Certifications</b></p>	<ul style="list-style-type: none"> <li>• Strict quality certifications required</li> <li>• Application of the new European Medical Devices Regulation (IVDR), which involves a long and complex certification procedure</li> <li>• In Italy, application of the DL 66/2014, which centralizes the public procurement process in purchasing Hubs, and of all the laws governing public tenders</li> </ul>
<p><b>Economies of scale</b></p>	<ul style="list-style-type: none"> <li>• Large players benefit from operational and financial economies of scale which enable lower production costs, higher margins and predominant positioning with key suppliers</li> <li>• Economies of scale enable a higher quality of the service</li> </ul>
<p><b>Know how</b></p>	<ul style="list-style-type: none"> <li>• High levels of know-how and track record of successful product launches required to obtain market credibility and product quality in order to be competitive in the market</li> <li>• Strong R&amp;D department to develop innovative products to be competitive in the market and to create client “look in” effect with specialised customised solutions</li> </ul>
<p><b>Sales &amp; distribution network</b></p>	<ul style="list-style-type: none"> <li>• Need for sales agents with an extensive knowledge of the market and the product on whom the customer can rely on</li> <li>• Practical knowledge of the Italian tendering process and regulation</li> </ul>

### Relevance



Sources: PwC Analysis

Competitive  
environment

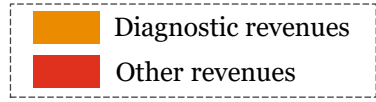
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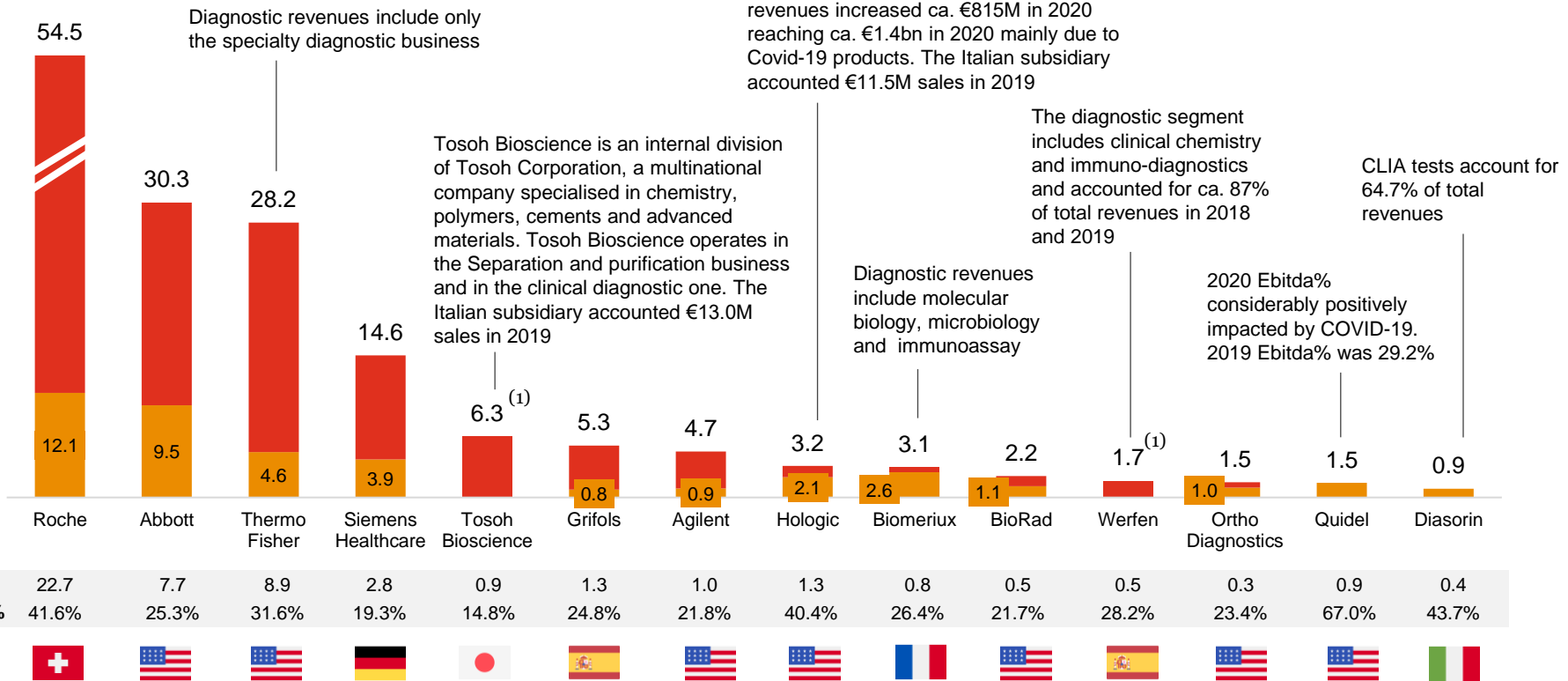


# The international IVD market is made up of two major clusters: large companies with highly diversified businesses, and smaller but highly specialized players in the IVD market

## Main international players in the global IVD market – Key Economics (2020 Consolidated revenues, €bn, %)



Diagnostic revenues include molecular diagnostics, Cytology & Perinatal and Blood Screening. Molecular Diagnostics product revenues increased ca. €815M in 2020 reaching ca. €1.4bn in 2020 mainly due to Covid-19 products. The Italian subsidiary accounted €11.5M sales in 2019



EBITDA	22.7	7.7	8.9	2.8	0.9	1.3	1.0	1.3	0.8	0.5	0.5	0.3	0.9	0.4
EBITDA%	41.6%	25.3%	31.6%	19.3%	14.8%	24.8%	21.8%	40.4%	26.4%	21.7%	28.2%	23.4%	67.0%	43.7%



Sources: PwC Analysis; Companies' financial statements and websites; Orbis

Notes: EBITDA data regards the whole company not only the diagnostic/IVD division in those with more than one SBU; 2020 Average annual exchange rates from Banca d'Italia have been adopted: \$/€ = 0.877, CHF/€ = 0.934; (1)Tosoh Bioscience and Werfen in 2020 do not provide information about revenues breakdown

# The largest companies in the Italian competitive landscape are mostly commercial subsidiaries of big international groups, with Diasorin, the Italian leader in the IVD market, as main exception



## Main players in the Italian IVD market – Key Economics (1/2) (2020 Sales, €M, %)

FY20 increase in sales comparing to FY19 sales

Operates through **Instrumentation Laboratory** in Italy. Foreign sales ca. €325M in 2020. The global company: 88% of tot revenues coming from the IVD SBU in 2019

2020 Ebitda% impacted negatively by COVID-19 (2019: 11.5%)

**Sales decrease** of ca. €6M from 2019. Part of the **Danaher** conglomerate since 2011, has a Life Science and a Diagnostics SBUs

Sales increase from 2019 mainly related to **COVID-19 product**. Foreign sales ca. €66M

2020 Ebitda% impacted negatively by Covid-19 (- 7.4% vs 2019). **Sales decrease** of ca. €2M from 2019. The global company: 85% of total revenues coming from the clinical application (IVD) SBU in 2020

Ca. €124M in Italy, ca. €58 abroad and ca. €289M of inter-group sales for distribution

Ca. €158M (48%) associated to the IVD diagnostic business. **Sales decrease** of ca. €15M from 2019

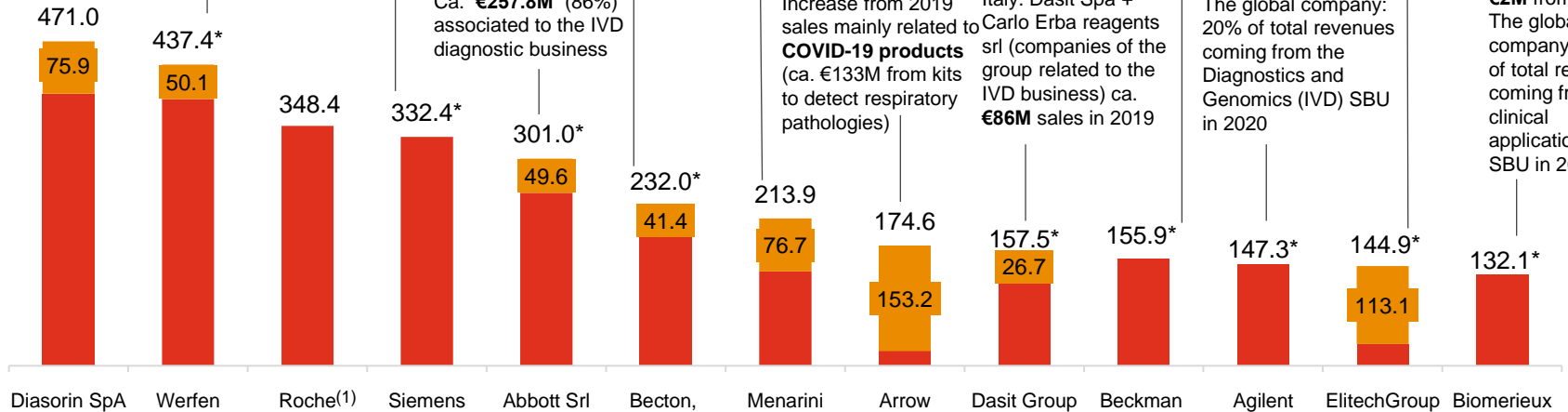
Sales increase from 2019 mainly related to **Covid-19 products** (ca. €102M). Foreign sales ca. €114M

Exclusive distributor of **Sysmex** (JAP; diagnostics; €2.6bn revenues in 2019) in Italy. Dasit Spa + Carlo Erba reagents srl (companies of the group related to the IVD business) ca. €86M sales in 2019

**Sales decrease** of ca. €10M from 2019. The global company: 20% of total revenues coming from the Diagnostics and Genomics (IVD) SBU in 2020

Sales fully in Italy. Increase from 2019 sales mainly related to **COVID-19 products** (ca. €133M from kits to detect respiratory pathologies)

Ca. €257.8M (86%) associated to the IVD diagnostic business



<b>EBITDA</b>	152.8	48.2	61.1	40.3	35.0	23.0	27.8	17.5	34.1	33.6	6.3	58.5	8.9
<b>EBITDA%</b>	32.4%	11.0%	17.5%	12.1%	11.6%	9.9%	13.0%	10.0%	21.7%	21.6%	4.3%	40.3%	6.7%



Sources: PwC Analysis; Italian companies' financial statements and websites; Orbis

Notes: EBITDA data regards the whole company not only the diagnostic/IVD division in those with more than one SBU;

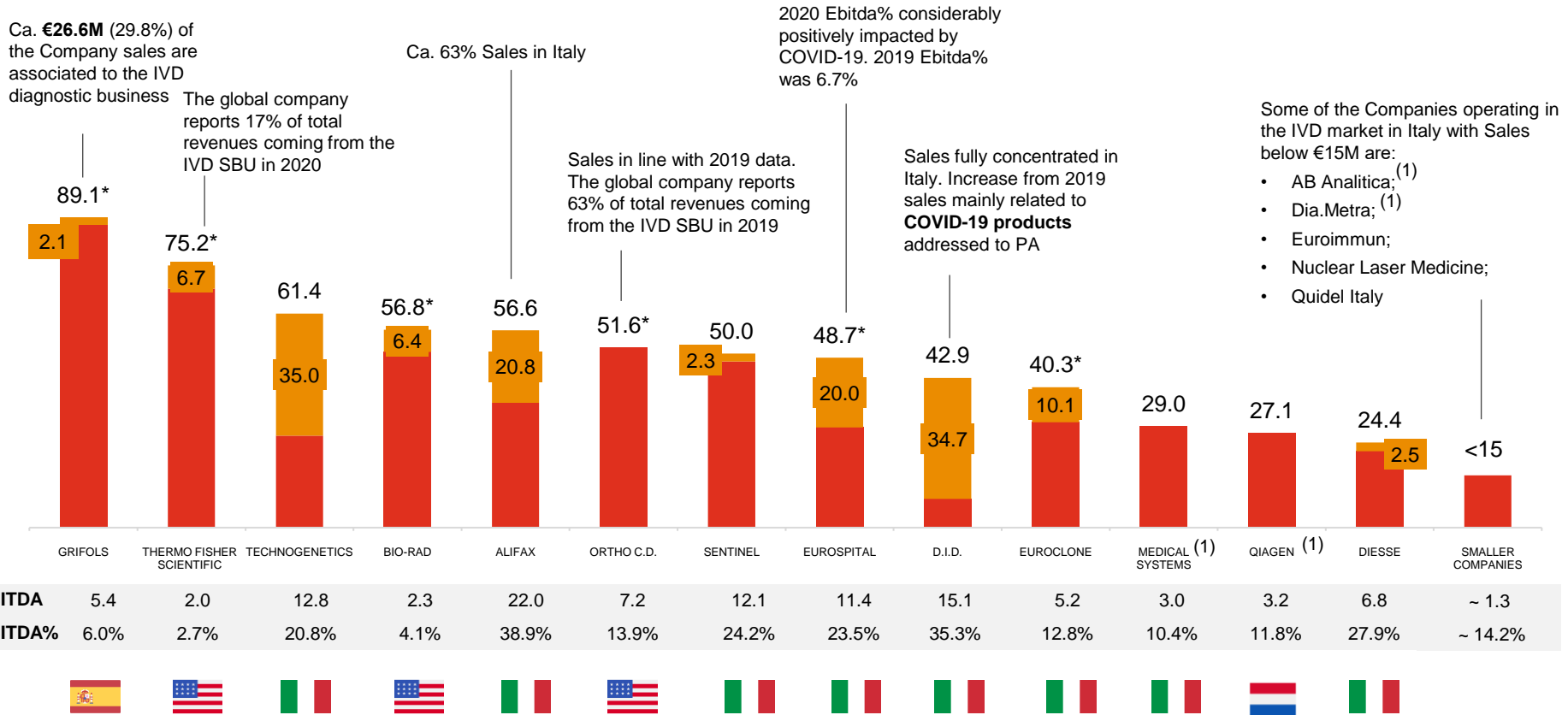
(\*) Companies whose data cannot be fully associated with the diagnostic/IVD business; (1) Roche Diagnostic I.a. consolidated data is 2019

# At the same time, the Italian market appears fragmented being populated by many local SMEs specialised in the IVD



## Main players in the Italian IVD market – Key Economics (2/2) (2020 Sales, €M, %)

FY20 increase in sales comparing to FY19 sales



Sources: PwC Analysis; Italian companies' financial statements and websites; Orbis

Notes: EBITDA data regards the whole company not only the diagnostic/IVD division in those with more than one SBU; (\*) Companies whose sales cannot be fully associated with the diagnostic/IVD business; (1) Companies referring to 2019 data (l.a.)



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