



In-vitro Diagnostics

Excerpt from the analysis from an M&A (mergers and acquisitions) perspective

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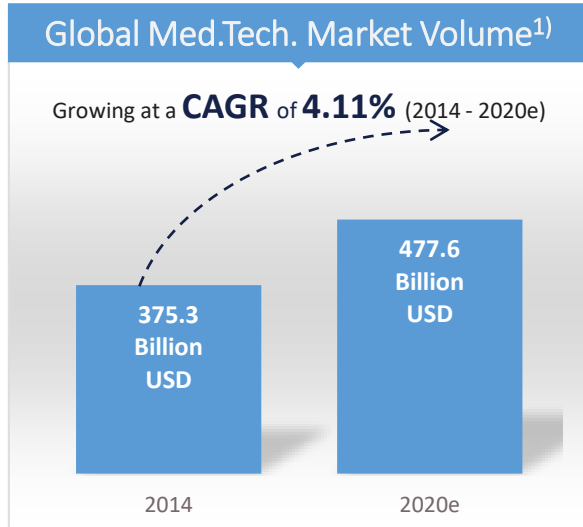
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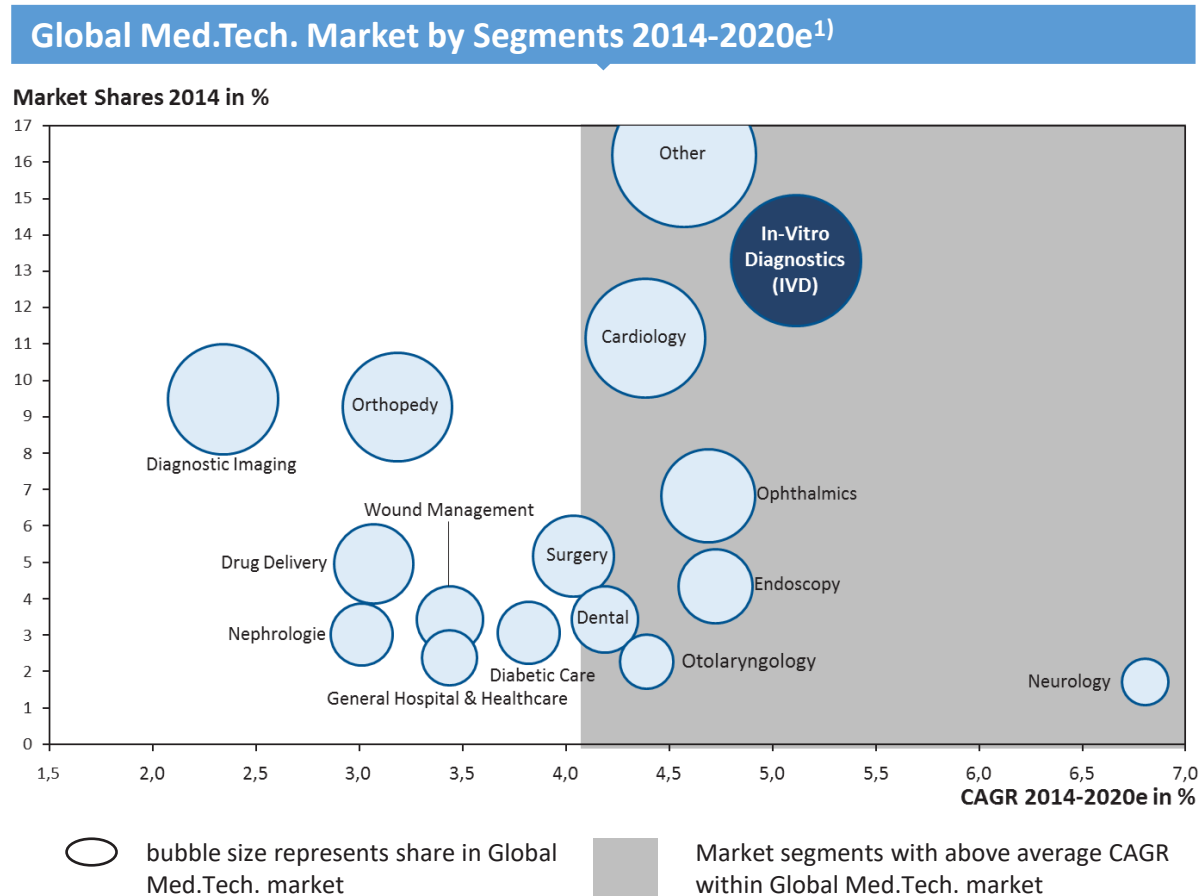
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In-Vitro Diagnostics (IVD) is one of the fastest growing segments within the Global Med.Tech. products market, ...

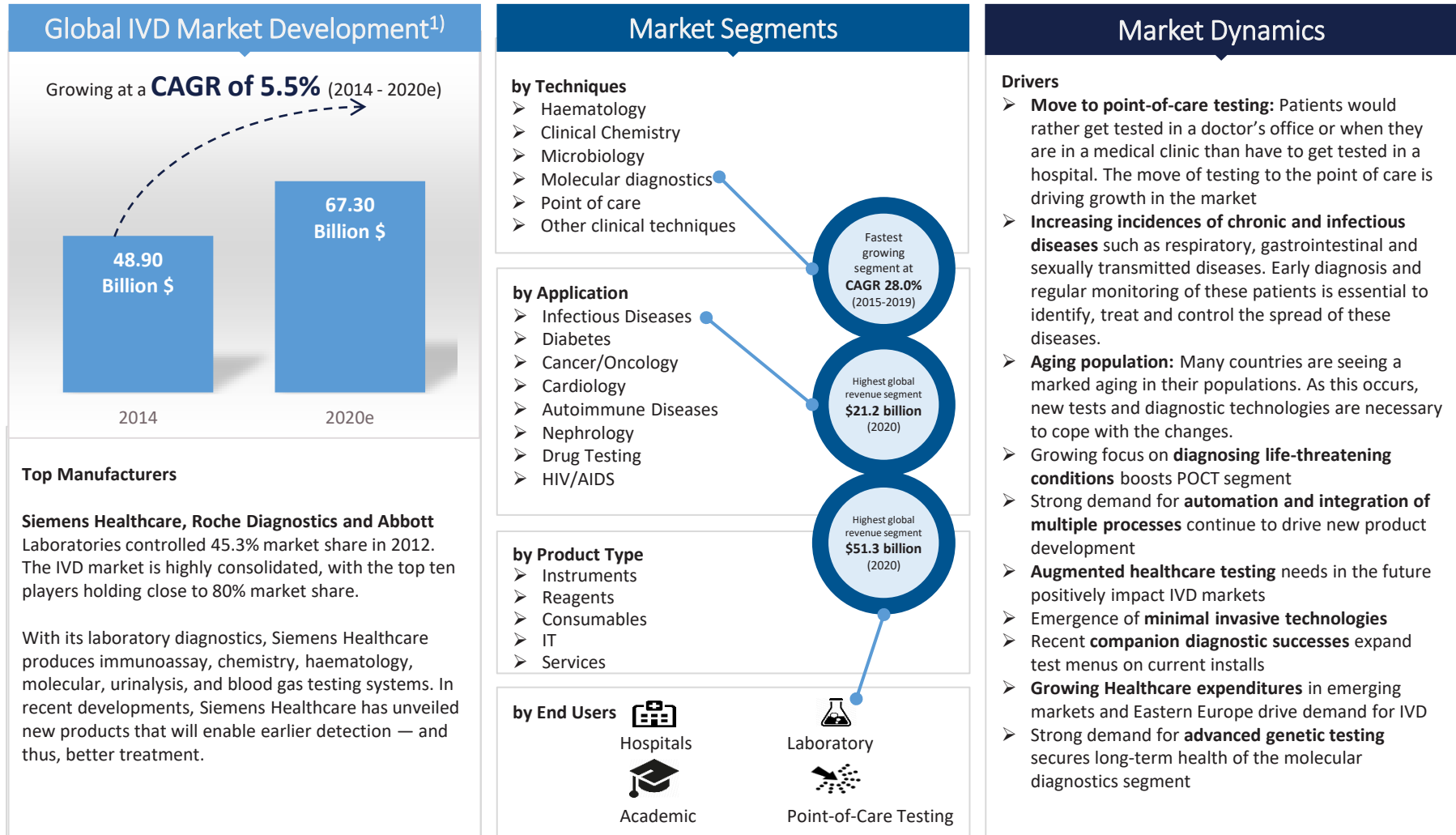


IVD	2014	2020e
Global Market Share	13.3%	14.1%
Volume (in bill. USD)	48.9	67.3
CAGR 2014-2020		5.5%



IVD is expected to be one of the main drivers of growth within the Med.Tech. market until 2020

..., sustaining positive dynamics in the global market for In-Vitro Diagnostics



Key areas of In-Vitro Diagnostic

Despite global economic and industry challenges, IVD-markets are growing robustly

In-Vitro Diagnostics

- IVD is a method of performing a diagnostic test outside of a living body in an artificial environment, usually a laboratory. Everyday examples of In-Vitro testing are blood checks for signs of infections, or urine analyses for the presence of glucose.
- IVDs are used in large-scale population screening, such as for cervical cancer, as well as for predicting whether a specific medicine or treatment will work on a patient. Patients with diabetes use IVDs regularly to monitor their blood glucose. They are also used to make or confirm a medical diagnosis, from confirming a pregnancy to checking for infectious diseases such as hepatitis or HIV.
- IVDs can be both automated systems capable of analysing large numbers of samples for multiple parameters as well as self-testing systems providing information directly to the individual performing the test.
- IVD purpose is not to have a direct therapeutic effect, but rather to provide valuable information on a patient's health status.

IVD types

- **Clinical laboratory testing:**
 - In case of high complexity the tests need to be run under specialist laboratory conditions; they are sent to laboratories, which then report back to the physicians.
- **Near-patient-testing:**
 - Carried out by healthcare professionals, such as doctors, nurses or paramedics, who do not require specialist laboratory facilities.
- **Self-testing:**
 - Designed for patients or individuals to be used by themselves; no requirements of specialist facilities, the user can usually interpret the information as per included instructions.

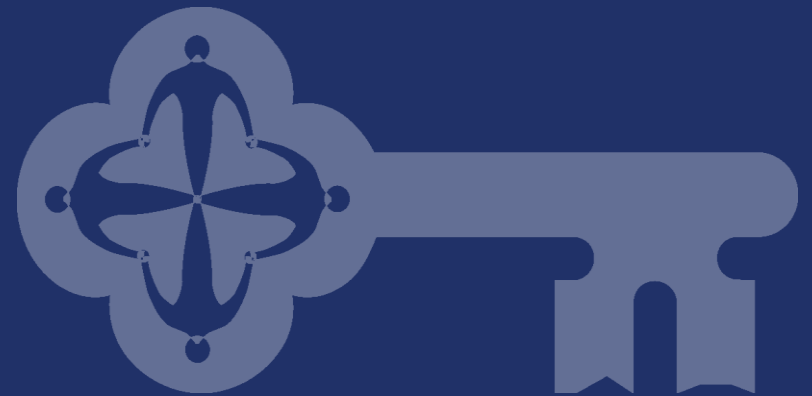
IVD products

- **Reagents:**
 - Solutions of highly-specific biological or chemical substances that are able to react with target substances in the samples; these process will result in an outcome that can be measured or screened.
- **Analytical instruments:**
 - Various machines and equipment automating the process and are used to bring samples and reagents together. Analytical instruments measure the result or other qualities and parameters in the samples.
- **Accessory products:**
 - Software used to run the instrumentation, and control solutions checking the systems performance.
- **Consumables:**
 - Vacuum and non-vacuum sample collection tubes, swabs, pipettes, cuvettes, dispensers, syringes, pumps, autoclaves.

Major IVD segments

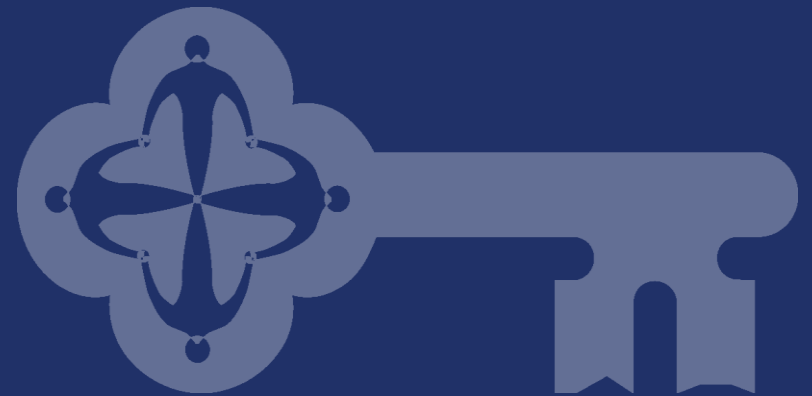
- Clinical chemistry – chemical tests for various components of blood and urine, also other techniques including the use and measurement of enzyme activities, spectrophotometry, electrophoresis, and immunoassay.
- Immunology / Immunoassay, a biochemical test that measures the presence or concentration of a macromolecule in a solution through the use of an antibody or immunoglobulin. The macromolecule detected by the immunoassay is often referred to as an "analyte" and is in many cases a protein facilities.
- Haematology
- Haemostasis
- POCT
- Molecular testing
- Microbiology
- SMBG

In-Vitro Diagnostics - Market Dynamics in Central Europe



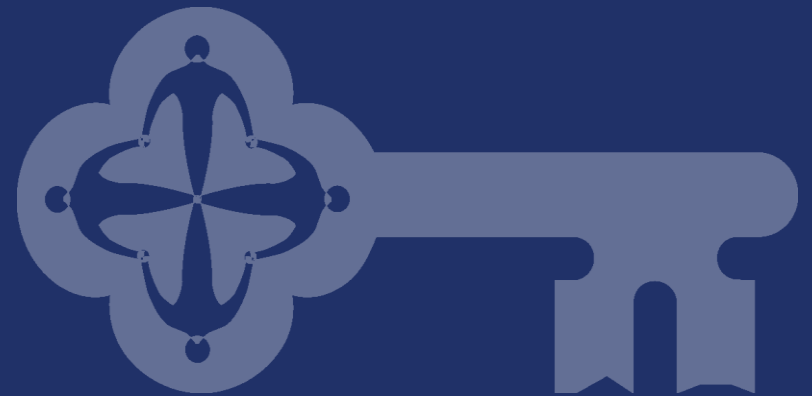
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In-Vitro Diagnostics - Market Dynamics Focus on DACH-region and United Kingdom



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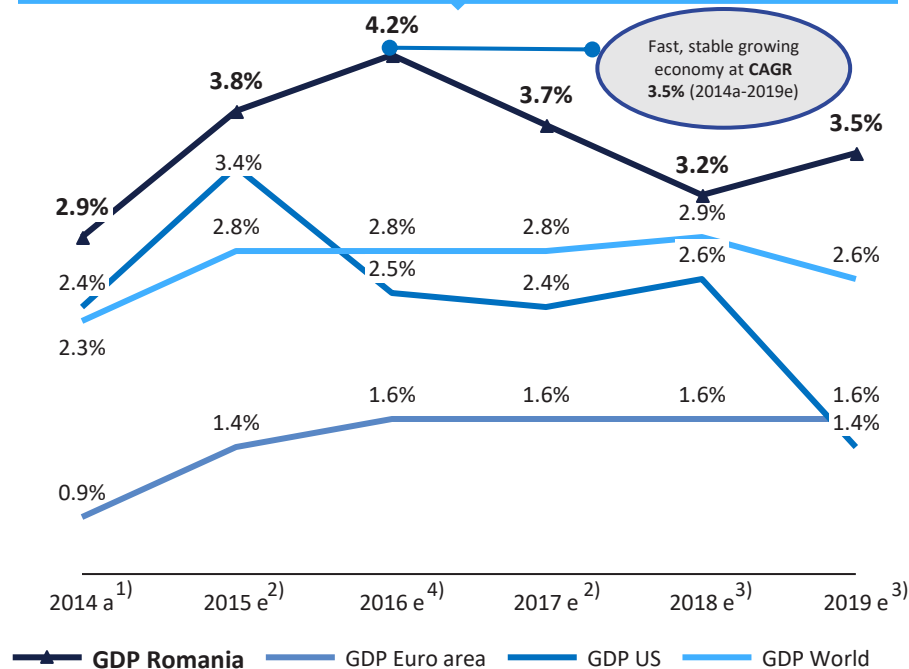
In-Vitro Diagnostics - Market Dynamics in South Eastern Europe



Romanian economy with strong growth potential

Increasing wealth and growth of Healthcare expenses per capita

Gross domestic product (GDP growth y-o-y in %)



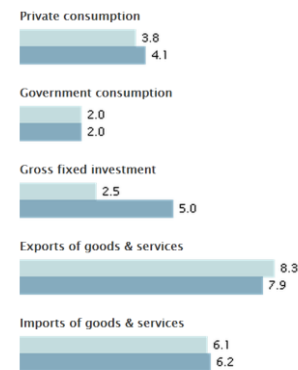
- 1) Economist Intelligence Unit estimate
- 2) European Commission report
- 3) Economist Intelligence Unit forecasts
- 4) Estimate National Statistics Office of Romania

Sources: Economist Intelligence Unit, Country Report Romania, March 19th 2015; National Statistics Office of Romania, 2016; European Commission – Commission Staff Working Document, 2016.

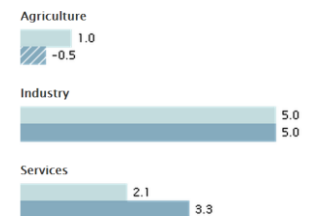
Overview and assumptions

- In the last 20 years, Romania has made considerable progress developing institutions compatible with a market economy.
- Joining the European Union (EU) in 2007 was a driving force for reform and modernisation (with further potential as it is expected to join EURO zone by 2019).
- Economy based on industrial manufacturing and services, with the EU as major export partner.
- The central bank now forecast year-end inflation of 2.1% in 2015, the lowest rate in post-communism.
- The European Commission continues to monitor Romania's progress under the cooperation and verification mechanism, with the focus on reform of the judiciary and tackling corruption.
- Romania's 20 million population has growing middle and upper classes with relatively high per capita incomes.
- Average net wage less than one-third from average EU-27 level.
- The expected GDP growth lies above European and global average, GDP real growth expected to exceed 3% in 2015.

Expenditure on GDP (% real change)



Origin of GDP (% real change)



Source: The Economist Intelligence Unit

Source: The Economist Intelligence Unit

Stable Romanian economy

Above average growth

Romanian Healthcare Market

Increasing focus on private insurance and medical services

Organisation of the Romanian Healthcare Market

- Romania now has a mandatory insurance-based financing model for Healthcare, involving contributions from employers (5.2% of gross wages) and employees (5.5% of the gross wages).
- The health insurance system is administered and regulated by National Health Insurance Fund (NHIF), a central quasi-autonomous body.
- Managed by National Health Insurance House through dedicated offices in each region, it is the pool of payments received through the mandatory state insurance scheme.
- The NHIF budget for 2015 is of EUR 5.1 b.
- The state-owned hospitals and clinics are still outnumbering the private facilities. Romania had some 472 hospitals in 2013, a number that remained relatively constant since the 1980's but the proportion of private facilities has increased from 0.5% in 1997 to 15% in 2013.

MoH

- The Ministry of Health (MoH) is responsible for drafting and implementing national policies and healthcare programs.
- Activity is financed directly through central State budget, including through directing certain tax revenues (alcohol, tobacco) towards various prevention and treatment programs, the National Healthcare programs dedicated to various diseases and conditions.
- The Ministry's budget for 2015 is EUR 1 b.
- Starting with 2013, equipment and supplies in the public system are purchased regardless of value by the Ministry of Health through a central procurement system, via a tendering process.

DPHDs

- District Public Health directorates (DPHDs) are the representative bodies of the MoH at the district level, operating in each of Romania's 41 districts. Supervising public health issues –application of sanitary norms, disease control, vaccine campaigns– under specific programs.

NHIF

- The National Health Insurance Fund (NHIF) sets the rules for the District Health Insurance Funds.
- (DHIFs), which have the responsibility of collecting funds and contracting with local providers, both individual physicians and collective hospitals and facilities.
- Since 1999, when DHIFs became entitled to contract with private providers, a move by many providers away from being 100% state-employed public servants is stated.
- Also, some of the public outpatient facilities (polyclinics) transitioned away from state-control to private operation.
- Polyclinics contract with the DHIFs on a fee-for-service basis.
- Budget for 2015 : € 5 b.

Public insurance

- Covered persons are entitled to a certain minimum package of medical assistance services under this scheme, plus subsidies for uncovered procedures, but only in state-owned medical units. Certain categories (children, dependents, war veterans and the disabled) are entitled to free public healthcare services.
- The available funds are under a continuous strain due to a chronic contributors-beneficiaries imbalance and out-of-pocket expenses are significant. Co-payment has been introduced for some hospital services in 2013, but at a very low level with a negligible impact for budget revenues.

Private insurance

- Still an undeveloped market, of some € 50 mio. in value and a small fraction of the total medical services market (public+private) estimated at € 5.5 b.
- Most dynamic segments are medical subscriptions, usually offered by companies to employees as benefits, that can be used with a single provider.
- Classic insurance policies are less developed, especially as they are more costly and usually do not cover medical problems existing at signing.

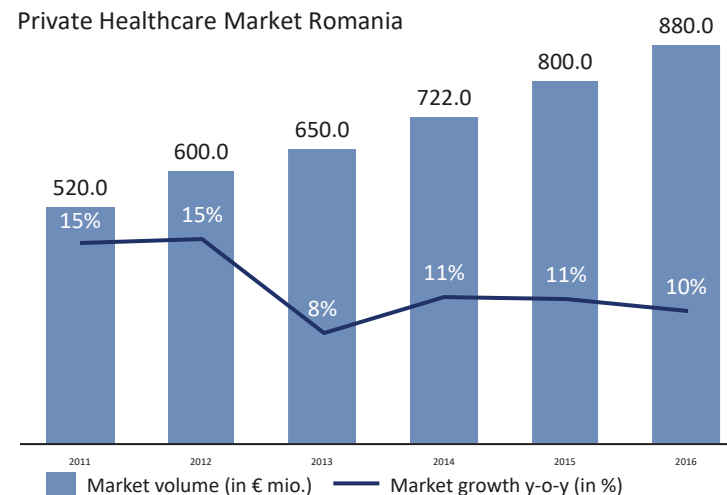
Private Healthcare in Romania

Still strong potential and dynamic for above average growth

Development of the Healthcare Market in Romania

- Total Healthcare expenditures (public+private) are estimated € 8 billion for 2015, representing 5% of GDP, which is still far lower than the EU average of 10%.
- Given its large population, Romania's Healthcare spending and IVD spending per capita are the lowest in the EU, i.e. there is an above average potential for increase due to higher GDP expectation.
- Strongest IVD-growth in Romania (+ 23% IVD-market volume in 2013, + 12% in 2014) within EU.
- The state-owned hospitals and clinics are still outnumbering the private facilities. Romania had some 459 hospitals in 2015, a number that began to increase after 2005, when the first private units were opened. The proportion of private facilities has increased from 0.5% in 1997 to 13% in 2015.
- Private Healthcare sector has a high growth potential due to the insufficient number, poor endowment and lack of specialisation of the public units and the growth potential is shifting more and more outside Bucharest and towards smaller cities

Development of Private Healthcare Market volume



Private Healthcare Sector in Romania

- Against a background of difficulties in public healthcare, private health insurances have grown constantly in recent years as Romanians increasingly seek sophisticated treatments at private hospitals and doctors under private insurance or out-of-pocket schemes.
- Private (optional) health insurance is still an underdeveloped market, of some EUR 50 million in value. Their most dynamic segment are the medical subscriptions, usually offered by companies to employees as benefits but limited in scope in comparison to classic insurance policies.
- The private medical services market for 2015 is estimated around € 800 mio., which represents a 11% growth over 2014. Until 2017/18 the market is expected to grow in a range of 10-11% p.a., with new openings of facilities.
- Private capacity is still small compared to the current demand for private medical services.

Private medical services centers in Romania

Top players Private Medical Services	# of centers
	2015
Medlife	45
Regina Maria	22
Gral Medical	20
Romar	18
Hiperdia	16
Medicover	12
Sanador	4

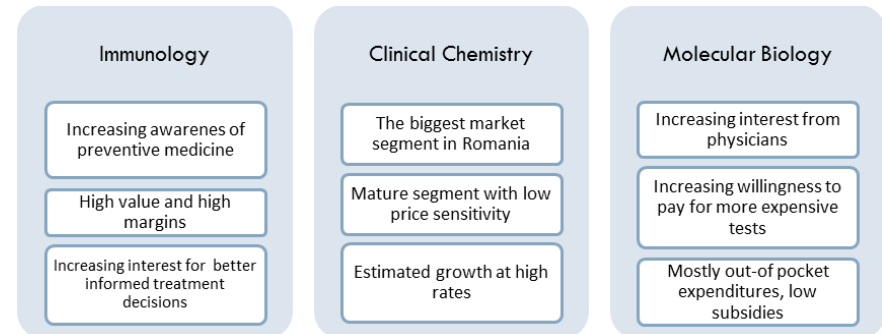
Market fundamentals & favorable Healthcare market dynamics strongly support further development of IVD segment

Romanian Healthcare Market Characteristics

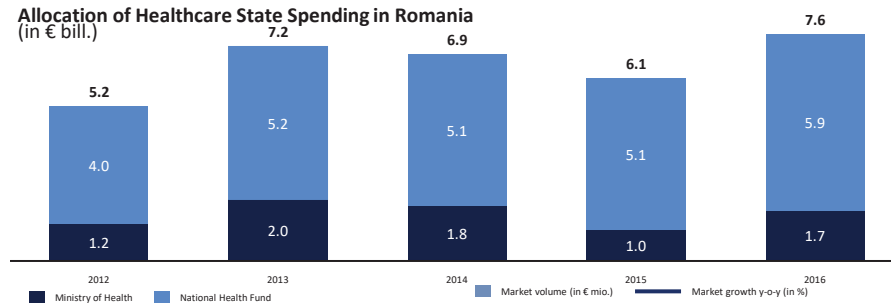
- Romania is one of the largest countries in Southeast Europe with a population of almost 20 million inhabitants (as of March 2016), growth in ageing population of app. 2%/year, decreasing birth rates and prevalence of the urban population.
- Total Healthcare expenditures (public and private) are estimated at € 8 billion for 2015, representing 5 % of GDP, which is still far lower than the EU average of 10%.
- IVD-growth in Romania is by far the most dynamic development within EU (+ 18% IVD-market volume in 2013, + 14% in 2014) .
- Private Healthcare sector has a high growth potential due to the insufficient number, poor endowment and lack of specialisation of the public units and the growth potential is shifting outside of Bucharest and towards smaller cities.
- Private medical services market for 2015 is estimated at around € 800 mio. representing 10% growth vs. 2014. Until 2017/18 the market is expected to grow in a range of 8-10% p.a.
- Nevertheless, the public sector is very attractive with respect to IVD growth potentials as the system evolves to European-level medical services.

Romanian Healthcare Market Trends

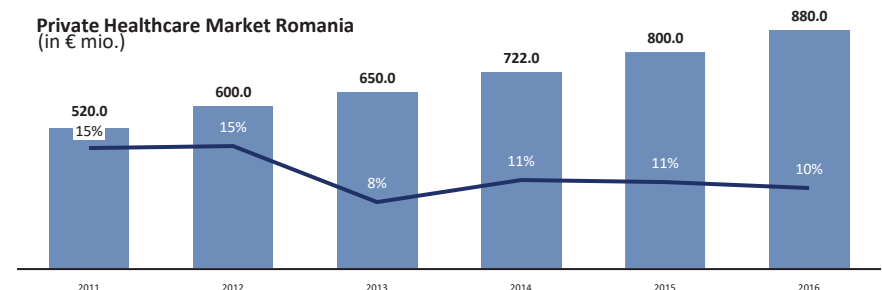
- National economic growth is pushing Healthcare expenditures per capita
- Positively developing demographics in emerging countries (life expectancy, ageing of population and health expenditure per capita).
- Increasing Healthcare focus on prevention over treatment.
- Romanian patients' growing preference for private laboratories.
- Labs favoring brands with strong reputation.
- Comprehensive governmental initiative to minimize corruption by consequent monitoring and severe punishment.



Allocation of Healthcare State Spending in Romania (in € bill.)



Private Healthcare Market Romania (in € mio.)



Impact of IVD-market trends in Romania

Booming private testing in addition to high impact of molecular testing and lab privatisation

IVD-market overview

- The diagnostic approach of pursuing laboratory tests has only developed over the last twenty years, allowing physicians to make better informed decisions.
- As such the Romanian IVD market has seen significant growth over the last decade and has been estimated at € 132 mio. in 2015 (CAGR 2011-2015: 13.3%), for the medium term (2015-2019) an market growth with an annual growth rate of 12.4% is expected.
- In the long-term, the Romanian IVD market should reach € 300 mio. in line with the 10% - 15% EU average of weight in the pharmaceutical market.
- Romania`s IVD expenditure per capita of € 4.60 is still significantly lower than the EU average of € 18.6.
- The public sector accounts for the largest part of the IVD market (about 70%) in comparison to the still developing private sector. However, the private sector is exhibiting a more dynamic expansion for the coming years.
- This growth of the private Healthcare market in Romania is related to the strong growth rates of IVD supplies within the private sector which is particularly driven by:
 - the opening of new private clinics and hospitals, especially in big cities
 - the fact that private clinics and laboratories are key customers for more costly equipment and tests, due to their better financial position or superior financial strength.
- Doctors and patients becoming increasingly aware of modern testing solutions like molecular- and point of care testing.
- It is expected that the private Healthcare sector alone will invest app. € 200 million until 2017 in new hospital and laboratory equipment with the private sector constituting about 70% of total Romanian Healthcare spend.

Historical development of IVD-Market 2011 – 2014 in Romania



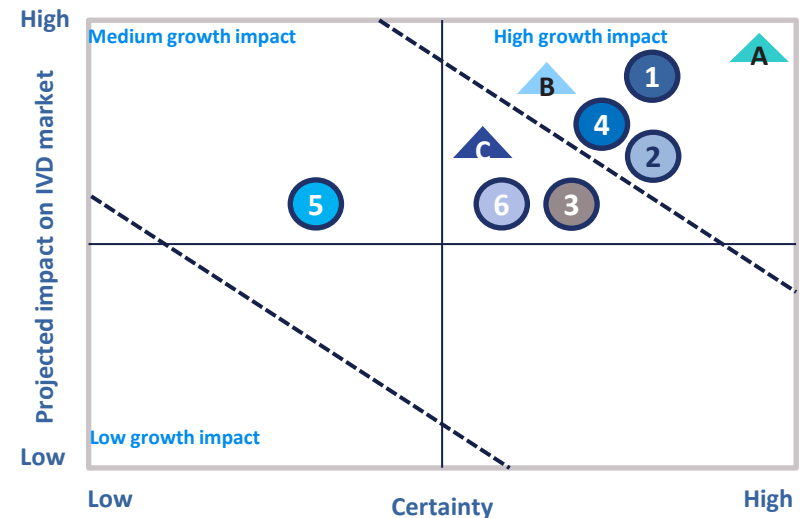
Source: European IVD-Market-Statistics Reports 2010-2013, Frost & Sullivan IVD-Market analysis Romania

IVD market driver in Romania

- A** Increased spending on medical services.
- B** Increased offer of private laboratory services.
- C** Shortage on prescribing pharmacists, i.e. shift to IVD-oriented doctors.

IVD key trends in Romania

- 1 Tests performed in private clinics remain a booming sector.
- 2 Molecular testing mean a key growth segment.
- 3 Increasing privatisation of public laboratories through consolidation.
- 4 Physicians sustaining awareness of IVD testing value.
- 5 Increasing awareness of personalised medicine.
- 6 Romanian physicians are familiar with POCT now.

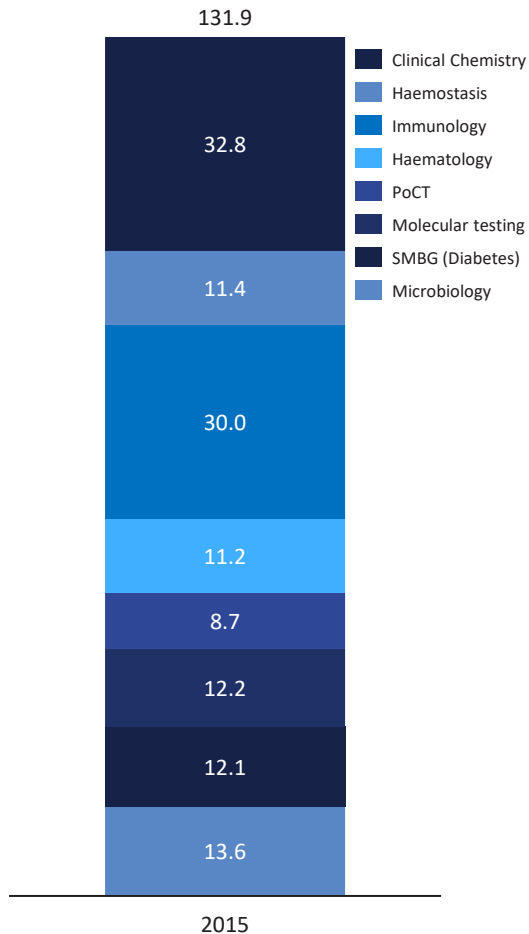


Romanian IVD-market analysis by segment

Molecular testing / immunology / microbiology with strongest growth potential 2015/20

Market volume split 2015

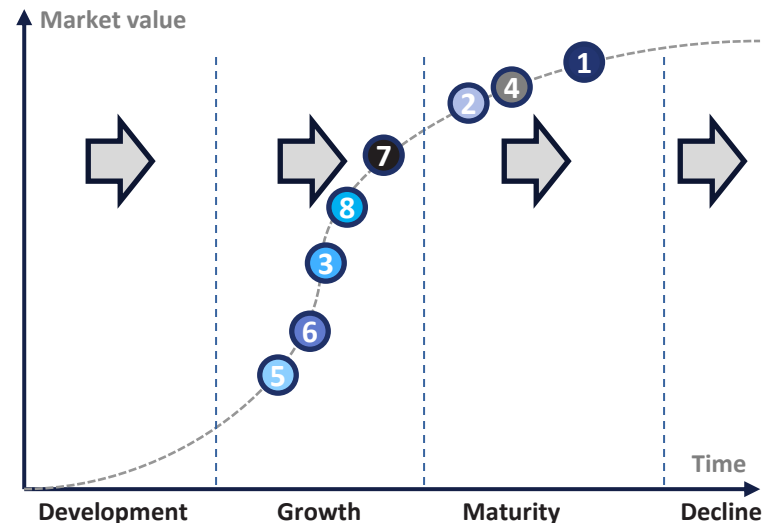
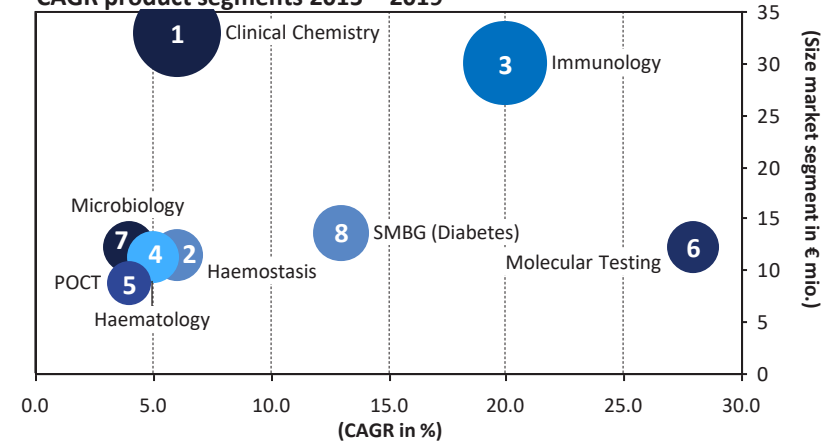
(in € mio.)



Development of IVD segments

- Clinical chemistry:** Late growth in terms of tests, sustaining growth due to investments from private sector and low price sensitivity.
- Haematology, haemostasis:** Mature segments, still with potential for growth due to aging population and its increasing access to medical tests.
- Immunology:** Growing at above average level, mainly due to increased focus on preventive medicine expected to sustain investment in automation laboratory solutions to cope with higher testing volumes.
- POCT:** Still in development stage as market region is more or less 5-10 years behind Western countries; positive trend driven by strong necessity for correct early stage diagnostic.
- Molecular testing:** Area of high growth, has garnered strong interest both among medical community as well as in the general public.
- Microbiology:** Late growth due to adoption of rapid tests (e.g. due to antibiotic resistance).
- SMBG:** Growing due to increasing rate of diseases such as diabetes and interest for screening and prevention, also replacement trend with some highly sensitive tests.

CAGR product segments 2015 – 2019



Source: European IVD-Market-Statistics Reports 2010-2013, Frost & Sullivan IVD-Market analysis Romania

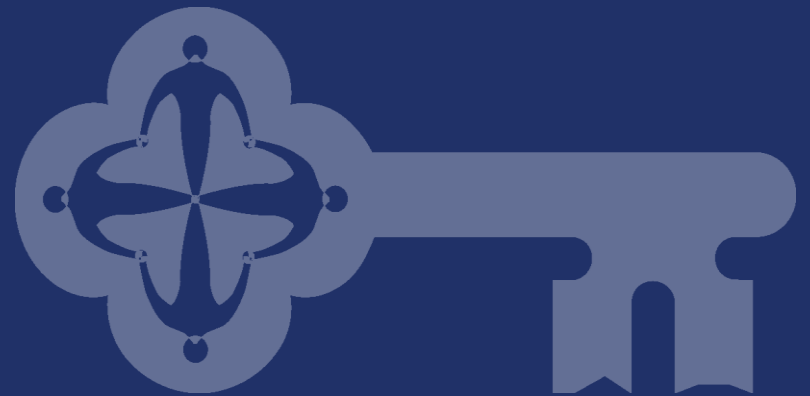
In-Vitro Diagnostics - Conclusions on Expected Future Market Dynamics

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In-Vitro Diagnostics – Technological Trends

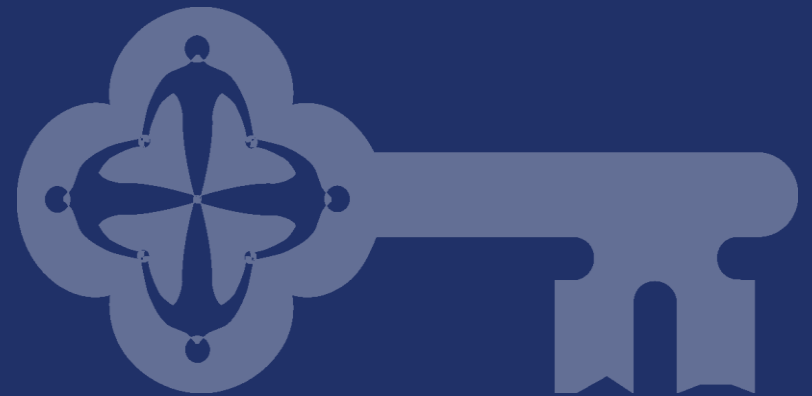
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In-Vitro Diagnostics - Competitor Analysis



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In-Vitro Diagnostics - Mergers & Acquisitions Analysis



In-Vitro Diagnostics - M&A Transactions

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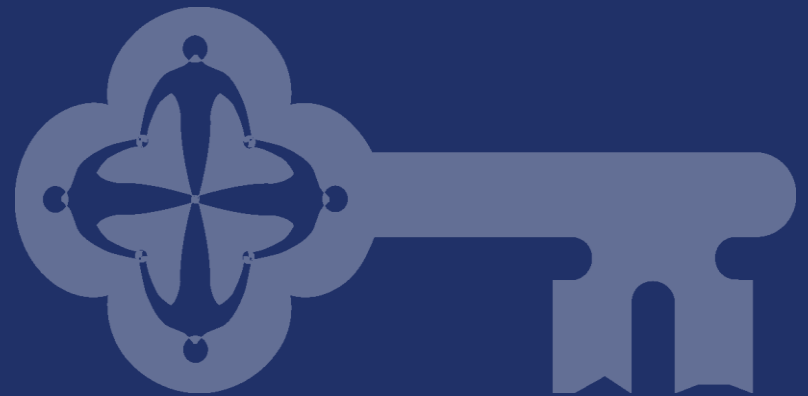
In-Vitro Diagnostics - M&A Enterprise Valuations

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In-Vitro Diagnostics - Assessment of potential Acquisition Targets (Longlist)

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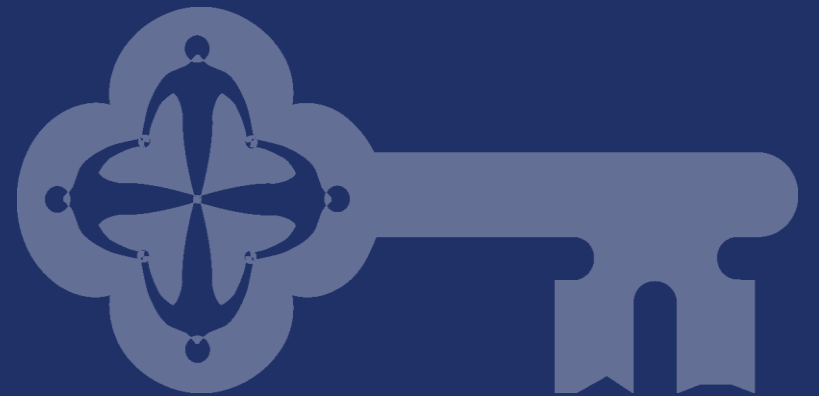
In-Vitro Diagnostics - Regulatory Assessment



In-Vitro Diagnostics - Regulatory Assessment

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Appendix



Global Med.Tech. Market 2014 - 2020

Global Med.Tech. Market by product fields 2014-2020

Segment	Global Market in US\$ b			Global Market Share		
	2014	2020	CAGR	2014	2020	Market share change in %
In-Vitro Diagnostics (IVD)	49,9	67,3	5,11%	13,3%	14,1%	0,8%
Cardiology	41,9	54,2	4,38%	11,2%	11,3%	0,2%
Orthopedy	34,8	42,0	3,18%	9,3%	8,8%	-0,5%
Diagnostic Imaging	35,6	40,9	2,34%	9,5%	8,6%	-0,9%
Ophthalmics	25,6	33,7	4,69%	6,8%	7,1%	0,2%
Surgery	19,4	24,6	4,04%	5,2%	5,2%	0,0%
Drug Delivery	18,6	22,3	3,07%	5,0%	4,7%	-0,3%
Endoscopy	16,3	21,5	4,72%	4,3%	4,5%	0,2%
Dental	12,9	16,5	4,19%	3,4%	3,5%	0,0%
Wound Management	12,9	15,8	3,44%	3,4%	3,3%	-0,1%
Diabetic Care	11,5	14,4	3,82%	3,1%	3,0%	0,0%
Nephrology	11,3	13,5	3,01%	3,0%	2,8%	-0,2%
Otolaryngology	8,5	11,0	4,39%	2,3%	2,3%	0,0%
General Hospital & Healthcare	8,9	10,9	3,44%	2,4%	2,3%	-0,1%
Neurology	6,4	9,5	6,80%	1,7%	2,0%	0,3%
Other	60,8	79,5	4,57%	16,2%	16,6%	0,4%
Total Global Med.Tech. Sales	375,3	477,6	4,10%	100%	100%	

- Global Med.Tech. market growth 2014-2021 with a CAGR 4.1%.
- IVD market growth CAGR 5.11%.

Source: EvaluateMedtech 2015

Definitions & abbreviations

€ / k€	Euro / thousand Euro
Δ	Delta / variance
%	Percent
a	actual (figure)
Admin.	Administration
app.	approximately
avg.	Average
b	Billion
BU	Business Unit
budg.	budgeted (figure)
c.	Circa
CAGR	Compound Annual Growth Rate
CAPEX	Capital Expenditure
CEE	Central and Eastern Europe
CEO	Chief Executive Officer
CF	Cashflow
Cont'd	Continued
Coord.	Coordination
Def.	Defined
DIO	Days Inventory Outstanding
DPO	Days Payables Outstanding
DSO	Days Sales Outstanding
DSVA	Local Authorities for Sanitary and Veterinary Control
e/E	Estimate
EBIT	Earnings Before Interest and Taxes
EBITDA	Earnings Before Interests, Taxes, Depreciation and Amortisation
EU	European Union
e.g.	Exempli gratia („for example“)
etc.	Et cetera
F&A	Finance & Administration
FC	Forecast
Fx	Foreign exchange
FTE	Full Time Equivalent
GP	Gross Profit
i.e.	id est („that is“)

IFRS	International Financial Reporting Standards
ISO	International Standardisation Organisation
IT	Information Technology
IVD	In-Vitro Diagnostics
Labs	Laboratories
m / mio.	Million
Mgt.	Management
MBA	Master of Business Administration
n.a.	not available
NE	Northeast
No.	Number
n.r.	not relevant
NWC	Net Working Capital
p	plan (figure)
p.a.	Per annum
POCT	Point-of-care-testing
Ppt.	Percentage points
QM	Quality Management
Rev.	Revenues
Ro.	Romania
Rom.	Romanian
ROS	Return-on-Sales
S&M	Sales and Marketing
SCM	Supply Chain Management
S.A.	Societate pe Acțiuni (Joint Stock Company)
SE	Southeast
SEE	Southeastern Europe
SMBG	Self-monitoring blood glucose
sqm	Square meters
SRL	Societate cu Răspundere Limitată (Limited Liability Company)
ST	Short-term
THE	Total Health Expenditure
TWC	Trade Working Capital
vs.	Versus
Y	Year
Y-o-Y	Year over Year

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