In Vitro Diagnostics
Healthcare Sector

Investment Thesis

We recommend an over-weight position for the In Vitro Diagnostics industry over the next year due to favorable macroeconomic drivers such as an aging population, numerous growth opportunities within the market and high end-users demand.

Drivers of Thesis

- **Demographics**: as the baby boomer generation begins to enter the 65 plus age category, and the average life expectancy is on the rise, the need for diagnostics will only increase.
- **Demand for innovation**: developments in artificial intelligence coupled with medical advances produces higher volume testing at reduced costs and increased quality of care.
- **Medical device tax**: a two-year extension for the moratorium on industry-wide medical devices tax signed into law on January 2018 will remain in effect until January 2020.

Risks to Thesis

- **Trade war**: the ongoing U.S and Chinese trade war is affecting the prices of necessary materials used in the production of medical devices.
- **Increase in unemployment rate**: higher unemployment causes more people to go without insurance and will also be a sign of a deteriorating economy.
- **Strengthening the dollar**: U.S companies with a global presence could experience a decrease in revenues and loss of market share.

Key Industry Statistics

<table>
<thead>
<tr>
<th>Key Industry Statistics</th>
<th>Overweight</th>
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<tbody>
<tr>
<td><strong>Market Cap (Top 6)</strong></td>
<td>(in Billions $)</td>
</tr>
<tr>
<td>Roche (RHHBY)</td>
<td>$227.79</td>
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<tr>
<td>Abbott Laboratories (ABT)</td>
<td>$127.08</td>
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<tr>
<td>Thermo Fisher Scientific (TMO)</td>
<td>$97.99</td>
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<tr>
<td>Danaher (DHR)</td>
<td>$76.61</td>
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<tr>
<td>Becton and Dickinson (BDX)</td>
<td>$66.67</td>
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<tr>
<td>Hologic Inc. (HOLX)</td>
<td>$12.72</td>
</tr>
<tr>
<td>Qiagen N.V. (QGEN)</td>
<td>$8.33</td>
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Key Industry Ratios

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<tbody>
<tr>
<td>EV/Sales</td>
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<tr>
<td>FCF Margin</td>
</tr>
<tr>
<td>P/E</td>
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<tr>
<td>Net Margin</td>
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<td>ROA</td>
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<td>ROE</td>
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<td>ROIC</td>
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12 Month Performance

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<tr>
<td>IHI</td>
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<td>S&amp;P 500</td>
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Source: FactSet

Industry Description

The In Vitro Diagnostics market is a subset of medical devices in the Healthcare sector that comprises companies who focus on developing, manufacturing and selling products to diagnose a broad array of diseases. This technique allows for personalized medicine and more efficient results as it focuses on each individual’s body tissue and blood to detect and monitor diseases. Some areas this can be applied to include oncology, infectious diseases, preventive care and prenatal.
EXECUTIVE SUMMARY

The In Vitro Diagnostics industry is a growing market due to the increased population at risk of developing diseases, technological improvements that offer better care and a demand for point-of-care diagnostic tests.

Total health care expenditure is estimated to be $3.3 trillion in 2019 and grow by a CAGR of 3.1% for the next five years.¹ The number of adults aged 65 and older will approximately reach 54.2 million in 2019, growing at a much faster pace than children and young adults.² In spite of the repeal to the individual mandate of the Affordable Care Act, the number of people with private health insurance is forecasted to slightly increase an annualized 0.1% until 2024.

Our overweight position for the In Vitro Diagnostics industry is based on positive economic drivers and several business opportunities within the scope of this field.

INDUSTRY DESCRIPTION

In vitro diagnostics are tests performed on specimens such as blood, tissue or urine with the goal of obtaining a diagnosis from assays in a controlled environment outside a living organism. The global In Vitro Diagnostics (IVD) market size was valued at USD 59.40 billion in the year 2017. It is expected to expand at a CAGR of 6.6% over the next six years.³ This industry can be classified by:

- **Product:** reagents, instruments, software and services.
- **Technique:** immunodiagnostics, hematology, molecular diagnostics, tissue diagnostics, and clinical chemistry.
- **End user:** laboratories, hospitals, point of care and academics.
- **Application:** infectious diseases, cancer, cardiac diseases, immune system disorders and other.

¹ Source: Statista
² Source: Statista
³ Source: Statista
Cancer

In vitro diagnostics and more specifically molecular diagnostics have changed the way cancer is diagnosed, monitored and treated. With advancements in genomics and proteomics now clinicians can observe molecular signatures to better diagnose cancer and offer personalized care. According to National Cancer Institute, approximately 38.4% of men and women will be diagnosed with cancer at some point during their lifetimes. It is essential to diagnose cancer in the early stages of development to improve patient outcomes. Molecular diagnostics plays a big role in this field.

Infectious Diseases

Infectious diseases are life-threatening conditions that affect billions of people across the globe. Most known diseases include HIV, STDs, tuberculosis, ebola, zika virus and malaria. Firms that address the need for reagents and easy to transport instrumentation will have a competitive advantage over peer companies. Emerging markets and developing countries often suffer outbreaks that take millions of lives. In 2017, there were an estimated 219 million cases of malaria in 90 countries.

Point of Care

In recent years, there has been an increase in the demand for point of care tests. Clinicians can perform diagnostic tests at or near patients’ point of care locations and provide quicker results. Companies have started to manufacture instrumentation that can be allocated in hospitals and include automated features for easier use.

This area is of great importance in developing countries where lines of care are not well established, and patients struggle to access diagnostic tests. However, reimbursement may be a challenge with limited purchasing power from fiscally squeezed health ministries. Furthermore, diagnostics devices used in a laboratory often need to be modified and/or miniaturized to be adapted to POC delivery, a task that can be difficult and expensive. Overall, this constitutes an opportunity area for companies trying to consolidate their market share in the industry.

Regulatory Authority

Products commercialized in the U.S are subject to the approval of the Food and Drug Administration under the medical devices’ regulation. Companies provide documentation and clinical studies to support the new device. It is a very tedious process that constitutes an essential step for the commercialization of a product.

For IVD products, the safety of the device relates to the impact of the device's performance, and in particular on the impact of false negative and false positive results, on patient health. In addition, these products are subject to the Clinical Laboratory Improvement Amendments of 1988.

RECENT DEVELOPMENTS

Protection of Products

All the companies operating in this segment are subject to complex laws regarding intellectual property, patents and licenses. Therefore, it is essential to protect products on every stage of its development to assure profitability of the firm.

The U.S Supreme Court has ruled against the patentability of two subject matters in the field of molecular diagnostics, creating uncertainty around what products can be protected. In addition, the legal framework around IP protection of diagnostic technologies has been changing over the previous few years and can be expected to continue to change in the foreseeable near future. Companies operating in different countries need to consider the laws that apply on each region.

Companies might license technologies to utilize in the manufacture of their products If those licenses were to be terminated, companies can suffer a big disruption on their business. Similarly, if companies lose exclusivity to technologies and reagents, they can lose competitive advantage.

Health Care Reform

President Trump and his administration promised to repeal and replace the Affordable Care Act that the Obama administration signed in 2010. This law was intended to widen health care coverage and protect those with pre-
existing conditions. In addition, a tax penalty was implemented in 2014 for those who were not enrolled in any health care plan. The Tax Cuts and Jobs Act that came into force in December 2017 not only reduced the corporate tax rate from 35% to 21%, but also eliminated the above-mentioned tax penalty. With a bipartisan Congress, further changes to this law will be more difficult.

Total enrollment for the Affordable Care Act insurance plan in 2019 is around 8.5 million, a 4% decline since last year. Less people under insurance coverages means less visits to hospitals, which in turn reduces total revenues for this industry. This decline in people insured can be balance out by an increase in employment-sponsored plans as long as unemployment rates remain low.

INDUSTRY TRENDS

Healthcare Spending

Total health care expenditure in the United States is estimated to reach $3.3 trillion this year and grow by a CAGR of 3.1% for the next five years. This growth is mainly driven by the aging population, PPACA and rising spending of healthcare per person. This upward trend can also be observed in other countries as promoting good health remains a global priority.

MARKETS AND COMPETITION

In Vitro Diagnostics is a subset of medical devices that has awaken the interest of healthcare providers as it offers targeted therapy at lower cost. This market is experiencing rapid growth due to technological improvements, more efficient diagnostics, and point of care testing. Medical experts stress the importance of early detention and precise diagnosis to improve the life of patients. IVD tests can be used to detect, diagnose, prevent and monitor diseases in various fields including oncology, infectious diseases, prenatal and preventive care.

Peer Comparisons

There are several consolidated companies including Roche, Abbott Laboratories and Danaher that account for a big portion of total market share. However, smaller companies specializing in niche areas are gaining territory and can be a potential threat. In Vitro Diagnostics is a global market thus having a broad geographic presence is essential to the profitability of companies.
Key players try to secure their market share by establishing partnerships with clinical laboratories and pharmaceutical companies, while smaller firms face the likelihood of being acquired by other diagnostic firms or private equity.

Abbot Laboratories

Abbot Laboratories is headquartered in Illinois and offers a diversified line of health care products including: branded generic pharmaceuticals, nutritionals, diagnostics, cardiovascular and neuromodulation products, and other. Geographically, the U.S accounts for 35.3% of their total revenues while the remaining is widely dispersed in countries like China, Japan, India and Europe.12

The Diagnostics segment provided 21% of total revenues in 2017. However, at the end of that year Abbott Laboratories acquired Alere Inc14 to become the leader player in Point-of-Care diagnostics, one of the most growing areas within IVDs segment. This movement will certainly give Abbot Laboratories a competitive advantage over its peers.

Danaher

Danaher is a medical company with headquarters in Washington D.C that offers equipment in four different segments: Life Sciences, Diagnostics, Dental and Environmental Solutions. They operate globally, with 37% of total revenues coming from the U.S and the remaining generated in China, Europe, Japan, India and Brazil among others.11

At the end of 2016 a subsidiary of Danaher acquired Chepeid, a global leading molecular diagnostics company that develops, manufactures and markets accurate and easy to use molecular systems and tests. The Diagnostics segment now accounts for 32% of total revenues generated.15

Industry Competitive Ratios

<table>
<thead>
<tr>
<th></th>
<th>Gross Margin</th>
<th>ROIC</th>
<th>P/E</th>
<th>Net Debt/Total Capital</th>
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<tbody>
<tr>
<td>Roche</td>
<td>69.92</td>
<td>24.42</td>
<td>20</td>
<td>12.18</td>
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<tr>
<td>Abbott Laboratories</td>
<td>58.45</td>
<td>9.7</td>
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<tr>
<td>Danaher</td>
<td>55.83</td>
<td>7.11</td>
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<td>23.59</td>
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<td>Thermo Fisher</td>
<td>39.51</td>
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<tr>
<td>Siemens Healthineers</td>
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<td>12.0</td>
<td>29.94</td>
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<td>Becton Dickinson</td>
<td>45.44</td>
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<tr>
<td>Sysmex</td>
<td>56.38</td>
<td>18.23</td>
<td>51.2</td>
<td>-25.32</td>
</tr>
</tbody>
</table>

Roche

Roche is a Swiss research healthcare company operating in two segments: Diagnostics and Pharmaceuticals. They generate 77% of total sales from pharmaceutical products while the remaining 23% comes from in vitro diagnostics. The latter segment has seen an increase in sales in 2018 due to their 8% growth in Centralized and Point of Care Solutions in addition to 5% growth in their Molecular Diagnostics business area. Roche has a solid international presence, covering Europe, Middle East, Africa, North America, Japan and emerging markets.12

In regard to mergers and acquisitions activities on the diagnostics segment, the company established business combinations with mySugr Gmbh, an Austrian private company focused on Diabetics care, and Vieweics, a private US company focused on optimization and analytics. As defined on their Annual Report, business combinations refer to the acquisition of rights to a single product or technology.13
Roche has an advantageous position over peers driven by higher gross margin, higher return over invested capital and lower net debt to total capital ratio. Taking on projects that generate positive cash flows and higher return than the invested capital represents a key milestone in the evolution of a company. Keeping lower levels of long-term debt reduces the pressure to use operating cash flows for repayment of debt, allowing the firm to use excess cash for acquisitions and/or research development.

**ECONOMIC OUTLOOK**

**Older Population Growth**

We are experiencing a rapid growth in the older population as the Baby Boomers began turning 65 in 2011. In 2015, 9% were aged 65 and older worldwide. By 2030, the older population will be about 12% of the projected total world population and by 2050, 17% of the total population of 9.4 billion will be 65 and older. An aging population coupled with higher life expectancy presents an opportunity for the health care sector. More people will demand medical assistance and preventive care to increase their quality of life. This phenomenon is taking place both in the US and worldwide.

**Cancer Incidence Rates**

Cancer diagnoses and death rates in the US have steadily declined over the last 20 years, yet this disease affects millions of people alone in the US. More than 1.7 million new cancer cases are expected to be diagnosed in 2019, and about 606,880 Americans are expected to die of cancer in the same year. Cancer risk increases with age, thus the rapid growing older population mentioned earlier will require more diagnostics.

**Trade War**

The US imposed tariffs on 818 Chinese imports worth $253bn from July 6, 2018, with additional tariffs of $267bn worth of goods being considered. In retaliation, China has imposed tariffs on $130bn worth of US products and may apply taxes to another 114, including medical devices. Right now, we are in the middle of a ceasefire and waiting for the resolution of this conflict. Industry growth is likely to slow as medical device manufacturers have their production lines disrupted, including those of general surgery products, in vitro diagnostic devices, and diagnostic imaging machines.

**Insured Population**

 Having insurance allows people to engage in preventive care and access medical services as it provides a financial protection against unexpected large bills. In 2017, 8.8% of the population in the U.S did not have insurance at any point during the year. Among those with health insurance, private coverage constituted 67.2% while government coverage accounted for 37.7%. This means that changes to government funded programs like Medicare, Medicaid and the Affordable Care Act would affect approximately 123 millions of people. Although there was not a significant shift from 2017 to 2018, there has been a sizable drop in the uninsured rate since the ACA was enacted in 2010. Between 2010 and 2018, the uninsured rate dropped from 16% (48.6 million people) to 8.8% (28.3 million people).

**Interest Rates**

During the Federal Open Market Committee meeting at the end of last month, the Federal Reserve decided to be patient on any interest rate moves, signaling some
uncertainty on the economic outlook. The Fed had previously stated their intentions to rise the interest rate to 3% during 2019, but it is currently at 2.40% with a target range of 2.25-2.5%. High interest rates affect capital structure of firms as equity becomes a more attractive option.

The graph above shows the difference between the 10-year Treasury Bill and the 2-year. This parameter has been declining in the last two years, thus shaping a flattening yield curve which could indicate the vicinity of a recession.

Government Shutdown

During the 35-day government shutdown, the FDA halted nonessential operations and did not accept new user fee applications. Those activities considered necessary remained funded by carryover user fees. Even though the government has temporarily reopened, new molecular diagnostic assays and instrumentations will likely experience some delay on FDA review activity.

A government shutdown can have clear short-term effects on the overall economy. Federal workers who are not getting paid will cut on their expenses, thus reducing consumer spending. Furthermore, with the disagreement on what constitutes effective border security between Congress and President Trump another shutdown could take place in the near future. If that were to occur, consumer confidence would decrease causing the economy to slow down once more.

In this field and gain market share. Offering products that can reduce overall healthcare costs will grant a competitive advantage over peers. Establishing the right partnerships, within the scope of your business portfolio, will provide steady sources of revenue.

INVESTMENT POSITIVES

- Favorable demographics: aging population increases the number of people at risk for developing diseases, thus increasing the demand for diagnostic tests.
- Innovation: companies leveraging on technological advancements to provide more effective and faster solutions to care.
- Legislation: the suspension of the excise tax and the reduction of income taxes at the corporate level incites companies to expand product lines and spend on research.

INVESTMENT NEGATIVES

- A decrease in the number of people with private health insurance coupled with an increase in the unemployment rate will result in an increase of the uninsured population. Consequently, the number of individuals demanding diagnostic tests will decline.
- Loss of international presence due to a strong dollar or unfriendly relationships with other countries.

KEYS TO MONITOR

Being a highly regulated sector, it is important to watch any updates on the Health Care Reform including bills that affect government funding for Medicaid, Medicare and the Affordable Care Act. Also, monitor the evolution of the currently suspended 2.3% excise tax on medical devices that is supposed to come into effect in January 2020.

Keep track of business areas where consolidated players in the industry are spending their Research and Development budget as the type of companies they are partnering/acquiring. This will dictate the direction of the industry.

CATALYSTS FOR GROWTH

Companies need to invest in innovation to be competitive in this field and gain market share. Offering products that can reduce overall healthcare costs will grant a competitive advantage over peers. Establishing the right partnerships, within the scope of your business portfolio, will provide steady sources of revenue.

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