# Industry Analysis Series: The New World of Medical Devices in China

On May 14th, 2020, rain was pouring hard in Wuahn. The residents of Wuhan's Jianghan District took their turns to go downstairs to take the new Covid-19 PCR test. This is the 1st day of the Wuhan Ten-day Battle for comprehensive community testing for Covid-19. Within ten days, each residential area had set up temporary testing sites and the whole city completed 6.57 million tests, achieving a preliminary mapping of the Covid-19 situation in Wuhan.

As of June 22nd, 2020, China's medical establishments completed over 90 million Covid-19 tests. The testing vendors increased from 2081 in Mar 2020 to 4804 in June. The PCR test technicians increased from 13900 to 28500. The testing capacity grew from 1.3 million tests per day in March to 3.8 million tests per day in June. Within three short months, China's Covid-19 testing capacity TRIPLED. This shocked the global media, with the Japan's Jiji Press noting that China's Covid-19 testing capacity was 130 times Japan's.

The PCR testing kit uses the fluorogenic probe to detect the Polymerase Chain Reaction. This is an example of Molecular Diagnostics, a sub-field under In Vitro Diagnostics. The pandemic has provided a never-before development opportunity to China's medical device industry.

According to Zhongtai Securities Research, in 2020, Chinese Medical Device public companies' revenue increased +60.15%, profits increased 157.35%, net profit attributable to equity holders increased 189.25%. This increase was especially true for In Vitro Diagnostic companies: thanks to Covid-19 related demand, there was explosive growth. The In Vitro Diagnostic companies' revenue increased 70.16%, net profits up 265.87%, with some company increasing net profit over 200 times yoy.

"If we call the 10 years prior to 2018 the "Ten Golden Years" for the domestic pharmaceutical companies, then 2018 was the start of the "Ten Golden Years" for domestic medical device industry." This was the declaration in the annual report by the seasoned China Medical Device expert Mr Xiyan Li.

The huge pickup in financial results is not just an one-off event for a selected handful of companies. Some companies moved from 2nd or 3rd tier to top ranks of the industry, while others are expanding globally on the back of the pandemic. The entire In Vitro Diagnostic industry is poised for explosive growth. We will address a few key topics in this article:

1. Explosive growth of medical device
2. What is In Vitro Diagnostics?
3. Industry chain for In Vitro Diagnostics
4. Import substitution for In Vitro Diagnostics

## 1 Explosive growth of medical device

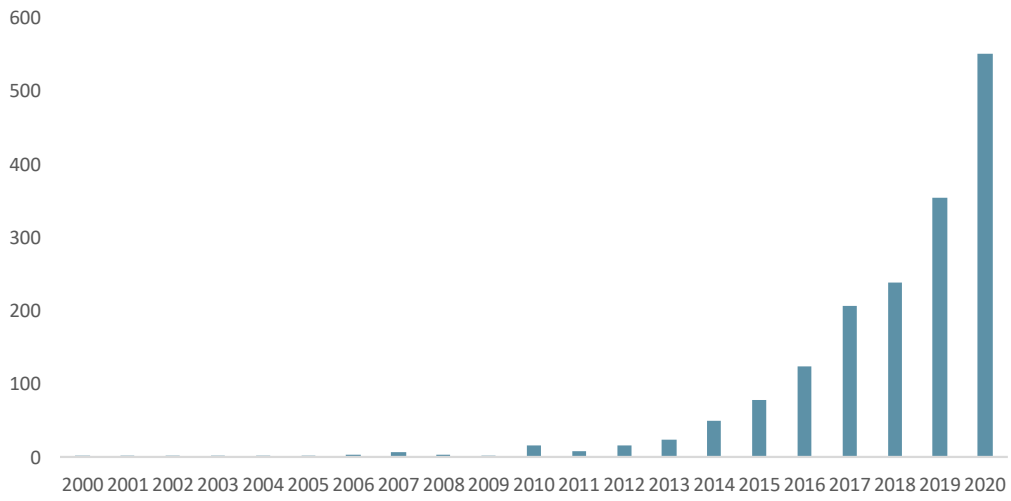
There are three main drivers for the fast development of the medical device sector: technology advancement, import substitution, and aging population. The external factors like policy and capital also play key roles.

On May 19th, 2015, China State Council published "Made in China 2025" strategy plan, where it listed biopharmaceutical and high quality medical device as one of top ten priority development sectors. Thereafter, numerous beneficial policies followed such as speeding up of registration approval process and improved efficiency of medical device review process. The accelerated review process shortened the time-to-market

cycle of innovative devices, which also increased the valuation premium for the pipeline products. With the supportive policy in place, the capital soon followed.

In 2017, Chinese medical device industry made investments of 20.574 billion RMB, or +66% vs 2016. Between 2012 and 2020, the average annual increase in medical device manufacturing investment was +60%. While this is behind the dramatic increases of hundreds of billions RMB for the biopharmaceutical industry, it is still impressive. Below is the chart for annual China medical device investment amount in hundred million RMB. Data source is ITjuzi.com and Rosefinch.

## 2001-2020年中国医疗器械投资额（亿人民币）




数据来源：IT桔子，朱雀基金

When we look at the relative ratio between medicine and medical device, the medical device growth is clearly higher than the medicine growth, though there is significant gap between the respective market sizes. Based on Rosefinch research estimates, the ratio in 2020 is about 2.2:1, which is higher than the global average of 1.4:1, and far higher than developed nations' 1:1. This means our medicine expenditure is still relatively high.

From industry development perspective, medical device industry has higher acceleration. When compared to medicine industry, medical device industry has the following three major advantages:

I. Shorter research and development cycle than medicine;
II. Longer product life span than medicine, with cumulative advantages for first-movers;
III. Doctors are familiar with using high-value consumable medical devices.

There are many factors in multitude of medical device standards, which makes it difficult to conduct Quality Consistency Evaluation. The qualitative differences can only be obtained through clinical data, doctor feedback, and product material. Since Quality Consistency Evaluation takes a relatively long period, and the consumables only have lift span of about two years, the product itself may already by phasing out by the frequent upgrades of the manufacturers. These high-value consumables have many differentiations and frequent mini-innovations, thus giving companies in this sector more attractive for future development.

Demand determines sales volume, market capacity, and industry ceiling. Supply determines pricing, protective "moat", and competitive landscape. The high-value consumables have wide differentiations and innovative products to satisfy different clinical needs. In Vitro Diagnostics is an inelastic demand where there are fast technological innovations, which makes it a worthwhile focus industry.

## 2. What is In Vitro Diagnostics?

IVD, or In Vitro Diagnostics means "in glass diagnostics", or external tests that detects disease, conditions or infections. They typically use body fluid, blood, or tissues to determine patient conditions. For example for the PCR, sample material from patient's respiratory tract is used to test if Covid-19 DNA is positive.

The earliest record of In Vitro Diagnostics can be traced to 430 BC, where Greek doctor Hippocrate used his senses to evaluate the urine sample. As biology science developed over the years, the IVD methods also advanced to become a key component of clinical diagnostics. Based on the principles and applications, IVD can be further divided: biochemical diagnosis, immuno-diagnosis, molecular diagnosis, urine diagnosis, microbiological testing and POCT or Point-Of-Care Testing. In China, biochemical diagnosis, immunediagnosis and molecular diagnosis are the three main diagnoses used. The Covid-19 PCR test and the popular genetic disease testing are part of the molecular diagnosis. Below is a summary of main diagnoses used:

### 体外检测的类型

| 诊断 | 基本原理 | 代表技术 | 常见应用 |
|---|---|---|---|
| 生化诊断 | 利用一系列生物化学反应对样本进行检测 | 干化学技术<br>免疫比浊技术 | 血常规，<br>肝功能，肾功能 |
| 免疫诊断 | 应用免疫学技术，即抗原与抗体的特异性结合来诊断病原体 | 主流：酶联免疫技术<br>新兴：化学发光技术 | 肝炎病毒检测<br>艾滋病毒检测 |
| 分子诊断 | 利用核酸杂交原理，检测样本中特异的 DNA 序列 | 聚合酶链反应<br>基因测序 | 病毒检测<br>遗传病基因检测 |
| 血液诊断 | 通过红细胞、白细胞、血红蛋白的含量等指标来分析血液成分 | 显微镜检测<br>血红蛋白测定<br>流式细胞术 | 血细胞检测<br>淋巴细胞检测 |
| 尿液诊断 | 通过分析尿液中红白细胞，微生物的含量等指标来判断尿液成分 | pH 检测<br>红白细胞计数<br>微生物测定 | 血尿检测<br>泌尿系统感染检测 |
| 微生物检测 | 通过显微镜直接观察判断或检测设备来判断微生物种类和数量 | 染色技术法<br>比浊法 | 真菌检测<br>细菌检测 |
| 即时检测（POCT） | 依照不同检测项目使用相应的检测原理 | 肌红蛋白测定<br>凝血酶源时间测定 | 心肌梗死标志物检测<br>血栓预防与治疗 |

资料来源：东兴证券，朱雀基金

Molecular diagnosis went through four major phases of historical development. The first phase was the DNA genetic test in the 1980's. During this phase, it was initially used clinically for contagious disease testing and organ transplant matching. The second phase was the advent of PCR technology since the 1990's, which made PCR a fundamental building block of molecular diagnosis. The third phase was the multi-indicator, high volume detection technology as represented by biochip technology. The fourth phase is represented by the 2nd generation genetic testing technology which can be applied to DNA testing for prenatal care, genetic disease, tumor, pathogenic microbe, etc. According to Roche Diagnostics, IVD can impact 60% of the clinical treatment plans, but with a cost of just 2% of total clinical bill.

## 3. Industrial chain for IVD

China's medical device industry went through three challenging development phases. The first is domestic distribution of foreign medical devices; second is import substitution; and third is independent innovation. The formation of an industry doesn't happen overnight, and requires at last one generation's diligent efforts. Those countries without a well-formed industry infrastructure will find it hard to compete against Chinese brands in the global medical device market.

From industry chain perspective, medical device industry has three main components: upstream parts manufacturing, midstream medical device and consumable manufacturing, and downstream clinical testing and usage.

For IVD, the key upstream raw material are the bioactive material and fine chemicals, which mainly include antigen, antibody, and diagnostic enzymes. These upstream raw materials are where the industry chokehold is. Take PCR as an example, almost all of the upstream material such as DNA polymerase and primer are imported. Because the production technology for such materials requires significant biochemical engineering capabilities, domestic companies are currently unable to manufacture. Therefore, at least for the time being, the pricing powers for such upstream material are held firmly in foreign manufacturers.

The downstream demand needs come mainly from medical examination and blood tests. The medical exams contribute to most of the consumption for the IVD, used mostly at hospital exam rooms, physical exam centers, independent laboratories, disease control centers, birth control stations, etc. The blood test is mainly used for blood bank tests, including various donation stations and blood-related product centers.

The midstream is made of most of the domestic IVD companies who produce and markets device and testing kits for various biochemical, immunological, blood cell, microbial, or molecular diagnostics.

| 产业链 | | 仪器 | 试剂 | 耗材 |
|---|---|---|---|---|
| 上游 | 原材料或零部件 | 仪器各零部件：<br>光源，电控器，显示器等 | 生物化学制品：<br>诊断酶，抗体，抗原，<br>精细化学品等 | 高分子材料：<br>PC, PET, PMMA 等 |
| 中游 | 三大产品 | 检测仪器 | 试剂 | 耗材 |
| | 代表产品 | 全自动生化分析仪<br>免疫分析仪<br>全自动化学发光仪<br>实时荧光定量 PCR 仪<br>血球计数仪<br>细菌分析仪等 | 生化诊断试剂<br>免疫诊断试剂<br>化学发光检测试剂<br>核酸检测试剂<br>血球试剂<br>微生物检测试剂等 | 采血管<br>样品杯<br>离心管<br>生化杯<br>比色杯<br>试剂盒等 |
| | 应用技术 | 吸收光谱技术<br>发射光谱技术<br>散射光谱技术等 | 生化反应技术<br>免疫诊断技术<br>分子诊断技术等 | 高分子材料加工成型技术 |
| 下游 | 医院诊断，体检中心，血站，独立实验室，家用检测等 | | | |

资料来源：2016 先进体外诊断技术峰会，东兴证券，朱雀基金

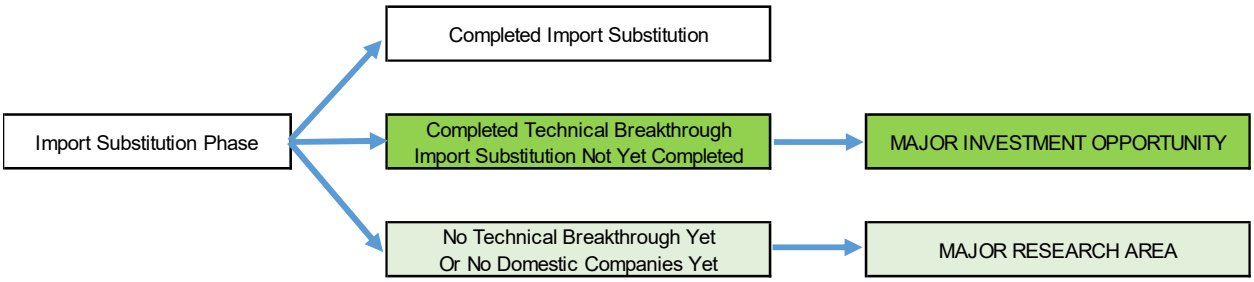
The top 50 medical device companies are mainly located in Europe, US, and Japan, while top 50 medication companies may be outside of these advanced countries. The barrier to successful medical device production is not just research and development, but also manufacturing, including a robust and comprehensive industry group. We're starting to see Chinese medical device companies making it to the Global Top 50 group, thus showing China is gradually building out the industry manufacturing capabilities. As companies lean on existing industry companies, there will be more and more medical device companies coming online. To the

latecomers to the industry buildout, because it takes literally generations of efforts and the right timing, it will be extremely difficult to have a credible competition to China's growing medical device industry in the immediate future.

The main reason for the successful import substitution of medical device industry is the engineer dividend. The Chinese engineers is one of the most low-cost and high-efficiency group across the globe. To the companies, develop new products can be most cost-effective and efficient than importing foreign products. In addition, the new product cycle can also be faster, thus ultimately succeed in import substitution.

## 4. Import substitution of medical device

Import substitution is one of the main drivers of China's development of medical device industry. Based on different competitive landscape, and different phases of substitution, the import substitution drive will eventually impact the company's valuation.




Source: Rosefinch.

In one scenario, China has completed import substitution with over 60% from domestic production, such as heart stent or biochemical reagent. From investment perspective, these are cash flow businesses and can be foundation for the company's rating upgrade. For example, in heart stent market, the import products account for over 95% of the market before 2004. The first domestic DES or Drug-Eluting Stent came to the market in 2004, with the second DES in 2005 and eventually expanded domestic DES market share to 59% in 2006, 65% in 2007, and 70% in 2008. This effectively ended the dominance of foreign DES by 2008, when three of the top six manufacturers of Heart Stents are domestic. As of 2017, the top three domestic brands have 24%, 23% and 20% of the domestic stent market, with the total foreign brands' market share at only 13%. Domestic brands are now the leading players in the heart stent market. In the field of biochemical detection, China has also completed the import substitution and entered the competitive "Red Ocean" phase. Unless there's new sectors of development, the single sector will hit its developmental ceiling quickly. Even if it's a nice cash-flow business, market will not value it aggressively because of likely intense future competition.

In the second scenario, domestic companies have completed the technical breakthrough, such as chemiluminescence, POCT, aortic stent, spine & joint, endoscopic consumables, etc. While there is not successful import substitution yet, these companies have done the technical breakthrough from 0 to 1, and are thus poised to monetize the products from 1 to N. The investment logic of the import substitution is relatively easy to confirm. By doing extensive industry analysis, tracking company data, comparing same industry players, the market gave a relatively healthy valuation for this deterministic logic in the past two years.

In the third scenario, in quite a number of sub-sectors, either domestic companies have not made the technical breakthrough, or no domestic company is active there. Some examples include: early tumor detection, CGM or Continuous Glucose Monitor, cardiac valve, endoscope, etc. From investment

perspective, we need to follow closely whether the companies can make the breakthrough from 0 to 1, thus enable them to capture future returns from their superior research knowledge.

In the past ten years, US stock market had 14 medical company stocks that had a market capitalization of over 10 billion USD and a return of over 10-times. Most of these companies are innovative companies, with 8 medical device, 3 new medicines, and 3 medical service companies. Medical device companies tend to grow over time, thus early investors can grow with the company and achieve considerable long-term investment returns. It also has its idiosyncratic risks. The biggest risk to medical device industry in China come from the policy reform of Centralization of Purchases. At national level, the centralization effort is mostly on heart stents, with an average cost reduction of about 50%. At provincial level, there was also a lot of centralization of purchases that led to reduction of as much as 97%.

Cost reduction in China's medical fields is a long-term trend, with bigger scale and wider range each year towards goal of basic affordable medical care for all. From a national regulator perspective, for products with a low barrier to entry, it makes sense to rid of unreasonable margins in the distribution process while keep some profits at production level. In order to keep reasonable profits, companies must therefore focus on product innovation. By proactively manage the product pipelines, the company can accommodate reduced prices on older products, while retain pricing power on new products to generate profits.

Look further afield, while domestic market will be under the long-term cost-reduction pressure, the global markets have better room for profit generation. The Covid pandemic gave Chinese companies an opportunity to enter the global stage, thus those companies with global capabilities are well worth our focus.