

# Review

## HORIBA Medical “Together, Let’s build the Future”

### Arnaud PRADEL



Figure 1 HORIBA Medical France Headquarter



Figure 2 HORIBA, Ltd.

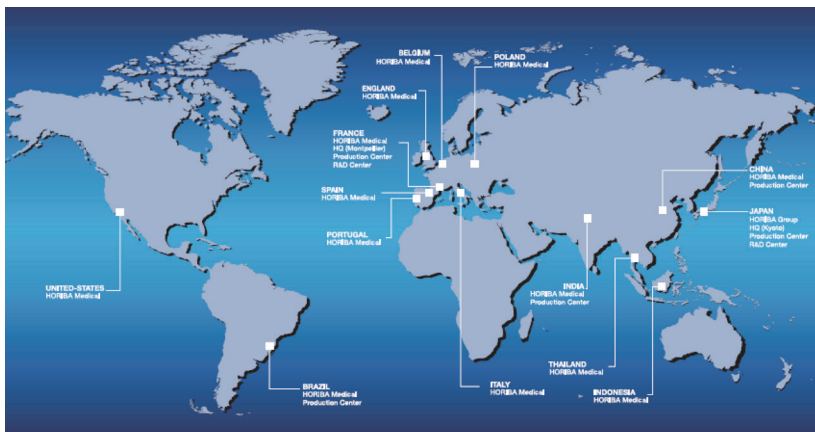


Figure 3 Global development of HORIBA Medical

### Introduction

According to this principal, HORIBA Medical is engaged into a long term mission, to provide laboratories with innovative products and services that exceed their expectations. We have built within our organization the sense of adaptation which, combined with 30 years of experience, brings a value to our dedication. (Figure 1, 2) Being the preferred partner in medical diagnostic solutions is not only our Vision but it also guides our daily decisions and choices. Quality is not just an assurance but our commitment to users; this is the foundation of a long term relationship. HORIBA Medical has clearly integrated this value on a continuous investment in product development, innovation and sustaining programs.

### A Global Presence

Present in over 150 countries on all five continents, with internationally recognized instruments and a leader’s ranking in most markets, HORIBA Medical is a world leader in the Hematology market. The strength of its distribution network coupled with its experience allows HORIBA Medical to operate efficiently in international markets. (Figure 3)

#### Expertise focused on customer service

Today, HORIBA Medical has over 1,100 employees across its sites and subsidiaries. It produces 7,500 instruments a year and it is now close to 10,000 tons of reagents produced annually. (Figure 4-8) HORIBA Medical also benefits from technologies patented by the HORIBA Group and synergies

between all its research centers throughout the world. Since ABX SAS joined the HORIBA Group in 1996, Medical segment sales have continued to grow exponentially to reach €207 million in 2013.

#### A global industrial expert

HORIBA Medical has reached international reputation thanks to its high standards in terms of innovation. Its flexible production units and pioneering R&D centers, it is always a step ahead in developing products, always responding to market needs. HORIBA Medical develops solutions which are adapted to its customers’ demands and anticipates

their needs thanks to technological creativity. Drawing on its extensive experience and its strong reputation in hematology, HORIBA Medical has become a major player in the IVD<sup>\*1</sup> industry. In addition, HORIBA Medical has entered into very specific industrial contracts (OEM) with major players in IVD, recognizing the quality of design and unique manufacturing capability.

\*1: IVD: In Vitro Diagnostic.

### Our vision: anticipate quality standards

Faced with increasingly high quality standards, HORIBA Medical sets out a creative and strong policy to address those by anticipating trends. Bold in technological skills, environmentally friendly, the company intends to maintain customer confidence and consolidate its worldwide position.

### Technological creativity

IVD specialists today have to design systems capable of carrying out increasingly complex tests while producing easier to interpret results. HORIBA Medical has risen to the challenge by intensifying its research efforts. The company aims to invest over 10% of its sales in R&D in the next few years. Many new concepts, that are unique, have been introduced in the field of IVD, including the most compact system on the market (Micros designed by HORIBA Medical). Over 40 “key” patent families have been lodged worldwide, covering all the technologies included in our testing systems. The finest successes are the ones that are shared.

### Health Care Throughout the World

As a service, health care is dealt with as goods and services whose consumption is not left to market forces alone. Some people question the pertinence of wide intervention of public authorities in the provision and financing of medical and paramedical care, but no one can deny the influence of government policies on the means of financing and provision. There is a strong correlation between the level of medical expenditures in a country and the amount of resources it produces or which are available for consumption and investment. This level of expenditure in the three large geographical areas termed “economically developed” (United States, Europe, and Japan) has been characterized over the last three decades by the following points.<sup>[1]</sup>

- The volume growth has steadily slowed down
- Specific medical inflation (that is, the growth rate of medical costs above and beyond that of general inflation) was lower when price increases were double figure (1970s), but reached new heights in the United States during the 1980s
- Actual health care services per inhabitant grew more rapidly than total household consumption

After the Second World War, and during nearly a quarter of a century, new financing mechanisms were introduced into all systems of health care on the basis of two assumptions.

- An unsatisfied demand for medical care existed due to financial obstacles



Figure 4 Production at HORIBA Medical France



Figure 5 Production at HORIBA Tec, Ltd.



Figure 6 HORIBA Instruments Brasil, Ltda.



Figure 7 HORIBA India Private Limited



Figure 8 HORIBA Instruments (Shanghai) Co., Ltd.

- The absorption of this demand would take some time, after which expenditures for health care would be stabilized or would decrease.

This second assumption has never come to be, if only because medical progress has brought about an unexpected demand for new forms of medical care. In actual fact, health care is also a luxury item, the demand for which grows as the standard of living rises. This trend continued throughout the 1990s in most OECD countries due to.

- Endogenous growth factors such as general ageing of the population
- Technical progress which increases the demand for medical services and the capacity to respond to it

However the consumption of health care develops.

- In favor of prevention and diagnosis as opposed to treatment
- Outpatient care increases to the detriment of hospitalization, new techniques appear; in particular in the fields of computer science, biotechnology, materials, etc

Thus, new fields of application exist which bring about, within the context of greater control of total health care expenditures, a shift towards the sector of prevention, of which diagnostic testing is one of the fundamental elements.

## What is IVD and What Contribution does it make on Global Health

### Definition and structure

Before interpreting the facts & figures of this market, we must first understand how it works and especially who are the contributors to the wealth generated. Just as the pharmaceutical market originally rooted in human and animal pathologies (diseases), but unlike pharmacy, IVD is not intended to treat or provide a therapeutic response. IVD consists of medical devices and products including disposable medical supplies, supplies and diagnostic products. These supplies include medical devices, reagents, consumables, instrumentation and other associated tests used in both laboratory and clinical research, those organizations allow the dosage of products, identification and quantification of bacteria, cells, viruses ... in biological media such as blood. While this remains a market and therefore potentially generates wealth, we can relate this activity to a much more noble purpose and which could be translated as follows:

*"Imagine a world where we will be able to tell patients whether they should take steps to anticipate the development of costly and painful diseases. Imagine telling them they do not need to take expensive drugs for life because they are not at risk of the disease. Finally, imagine a predictive form, personalized and preventive medicine this is not just a dream but a vision to work for, as quickly as we can".*

*Dr. Elias A. Zerhouni*

The IVD market is governed not by the consumer with income based on supply and demand, but by "payers". These payers who are financially responsible for the cost of health care are also important regulators of the

market and are often state authorities (public health authorities). Although these payers do not always determine whether a product may be legally marketed (other regulatory authority), they are artificially political power in charge of determining which products are successful in the market and those who do not.

**Geographical breakdown**

The IVD market is a global market, its potential and its dynamism is related to different factors which can be categorized into two main categories: Economic power, which is generally fairly homogeneous by major regions of the world, the industrialized countries, the BRICS<sup>\*2</sup> and the rest of the world knowing that the rest of the world represent only 10% of the world market. More and more markets are divided in more specific ways and we begin to see special attention for EMEA.<sup>\*3</sup> (Table 1 and Figure 9)

The regulatory authority, which, unlike the economic power, is closely related to the structure of the country and can be extremely restrictive. In the case of the USA for example, the FDA<sup>\*4</sup> must give its prior clearance approval before any marketing of diagnostic products can proceed and that clearance requires a very lengthy and expensive clinical study process. In all cases, even in developing countries there is a trend toward strengthen regulations and pre-registrations. Depending on whether the country is highly regulated (USA, Europe) or not, despite the economic difficulties and increasing regulatory requirements, the IVD supports a strong growth market twice the rate of the global pharmaceutical industry. This is directed by political will (payers), which want to develop a more predictive “medicine” bringing significant savings by increasingly relevant diagnoses associated with a truly targeted therapy (global decrease in exploratory therapies and broad spectrum).

The IVD market is estimated to approximately 53 billion dollars in 2012 and should reach \$ 69 billion in 2017, which brings us to a CAGR<sup>\*5</sup> of 5.5%. (Table 2) This influential three-dimensional position (political, economic and regulatory), makes it difficult to forecast and determine market trends knowing that at any moment one of these entities can change the situation. However it seems that analysts agree on the following points which increase with global market potential.

- The aging of the population and the development of chronic diseases (cardiovascular disease, cancer, diabetes ...) potentially will result in steady increases
- The implementation of preventive health policy (as explained above)
- The development of infectious diseases related to the globalization of trade
- The development of resistance to antibiotics and anti-virus
- Pressure on health care costs in developed countries / increase the level of care in developing countries

\*2: BRICS: Brazil, Russia, India, China, South Africa

\*3: EMEA: Eastern Europe, Middle East, Africa

\*4: FDA: Food and Drug Administration

\*5: CAGR: Compound Annual Growth rate is a business and investing specific term for the geometric progression ratio that provides a constant rate of return over the time period

Table 1 World IVD market size (2012)

| Region        | Market Size (\$ Million) |
|---------------|--------------------------|
| North America | \$22,949                 |
| EMEA          | \$18,120                 |
| Asia Pacific  | \$5,391                  |
| Japan         | \$4,261                  |
| Latin America | \$2,093                  |
| Total Market  | \$52,814                 |

Source: Enterprise Analysis Corporation 2013

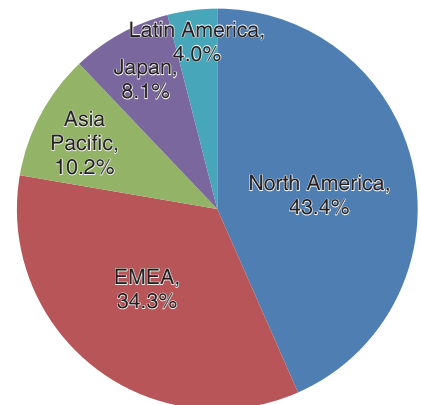


Figure 9 World IVD market share (2012)  
Source: Enterprise Analysis Corporation 2013

Table 2 IVD market growth by segment (2012-2017)

| Segment               | 2012 (\$ Million) | CAGR (%) | 2017 (\$ Million) |
|-----------------------|-------------------|----------|-------------------|
| Central Laboratories  | \$34,030          | 5.5%     | \$44,474          |
| WBG                   | \$8,816           | 2.3%     | \$9,884           |
| POCT                  | \$5,346           | 8.1%     | \$7,892           |
| Molecular Diagnostics | \$4,622           | 8.0%     | \$6,804           |
| Total Market          | \$52,814          | 5.5%     | \$69,054          |

Source: Enterprise Analysis Corporation 2013

Table 3 IVD market growth by segment in laboratories (2012-2017)

| Discipline              | 2012 (\$ Million) | CAGR (%) | 2017 (\$ Million) |
|-------------------------|-------------------|----------|-------------------|
| Immunoassays            | \$12,597          | 6.0%     | \$16,893          |
| Clinical Chemistry      | \$6,545           | 3.9%     | \$7,926           |
| Clinical Microbiology   | \$2,742           | 5.0%     | \$3,504           |
| Anatomic Pathology      | \$2,551           | 9.3%     | \$3,988           |
| Hematology              | \$2,489           | 5.6%     | \$3,268           |
| Coagulation             | \$1,532           | 5.0%     | \$1,957           |
| Immuno-Hematology       | \$1,480           | 4.4%     | \$1,837           |
| Blood Screening Immuno  | \$1,324           | 3.9%     | \$1,605           |
| Critical Care (BG/E)    | \$697             | 3.8%     | \$838             |
| Clinical Flow Cytometry | \$641             | 6.9%     | \$895             |
| Urinalysis              | \$470             | 4.2%     | \$577             |
| Others                  | \$962             | 4.2%     | \$1,186           |
| Total Market            | \$34,030          | 5.5%     | \$44,474          |

Source: Enterprise Analysis Corporation 2013

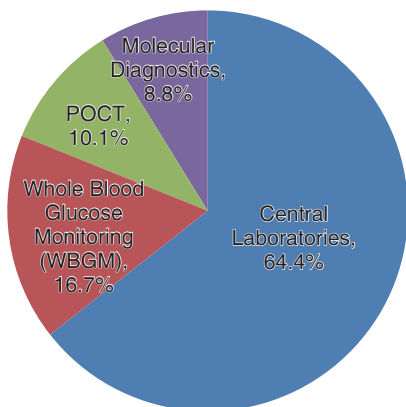


Figure 10 IVD market by segment (2012)  
Source: Enterprise Analysis Corporation 2013

### A clearly segmented market

Historically, the IVD market is segmented in several ways in order to search within single customer homogeneous subsets of customers which generally are characterized by.

- Separate expectations vis-à-vis a class of goods or services : the disciplines
- Special purchases conditions : types of test structures (Table 3, Figure 10)

In all cases, the segmentation is easy and especially very particularly suitable for identifying the needs of each segment. Combine the two if you want to be particularly relevant and offer appropriate products and services. Similarly some disciplines can be combined by their principles of action and similar detection (Chemistry & Immunology), which enables businesses to consolidate their R & D and especially offer a wide range of products while

using their own knowledge base.

This type of structure segmentation can be differentiated by their working methods, but also the conditions of purchase. We can see such differentiation between central laboratories which are often managed by the purchasing center, hospital administration, or the director/owner of the laboratory. ECF/ POL (Offices of physicians allowed to biological testing - USA, Switzerland etc.) they are particularly focused on “waived” testing. These tests are identified by agencies as being simple to perform, to the point where it is extremely rare to get an incorrect result, and if an incorrect result is obtained, it presents no risk to the patient, some of them are also approved for use at home.

The discipline segmentation (central laboratories) is particularly suited to the intrinsic expertise of companies (suppliers), in fact the differences in the principles of measurement and detection are so far away or so close that the ability / desire to offer products of a discipline or another is particularly strategic for business.

The fields of application are quite large and there is a thin line between wanting to find the most possible; and proposed “turnkey” solutions while risking credibility if it is a product line endangers patients’ lives; or stays specialized in a particular area and cannot offer a complete solution to customers wishing to obtain a solution in multiple disciplines. We can also see that not only the size of market segments by discipline is not the same, but also the profit generated (bubble size) is different i.e. immunology. (Figure 11, 12)

The IVD business model is similar to the type used for printers where the basis of placement of medical devices with minimal margins and then generate income on the consumption of reagents, and consumables necessary for their operation. Small “Low cost” devices represent the largest number of investments especially in BRICS However, the biggest source of profit is generated on large systems which consume higher volumes of reagents.

There is now a change in the approach to laboratories that tend toward a business model which is a little different, consisting of “packaged deals” where the entire solution including the device, reagents, controls and cost of service required for five years using a billing of a “cost per test”. This allows laboratories to avoid heavy investments and costs in operations. This allows companies not only a greater funding capacity but also innovative financing

### Hematology Market Growth

The Hematology segment of the IVD market was at \$ 3.69 billion in 2012 (including blood typing) CAGR (Compound Annual Growth Rate) of 7.2% from 2012 to 2017. (Figure 13) The need for greater efficiency in the lab, created a demand for automated analyzers for a complete leukocyte differentiation, especially in the United States and Europe. However, tight monetary and regulatory delays in both markets resulted in stunted growth. Laboratories in China and Asia-Pacific modernized with a “creation” market with small devices in laboratories called “traditional.” In addition, China and India, had industrial target opportunities in emerging markets like the Philippines, Vietnam and Thailand, which currently show strong double-digit growth.

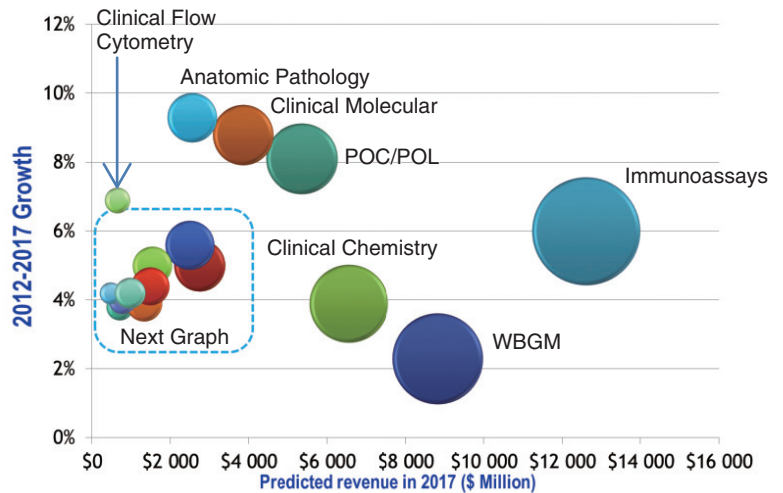


Figure 11 Expected revenue and its growth by segment (2012-2017)  
Source: Enterprise Analysis Corporation 2013

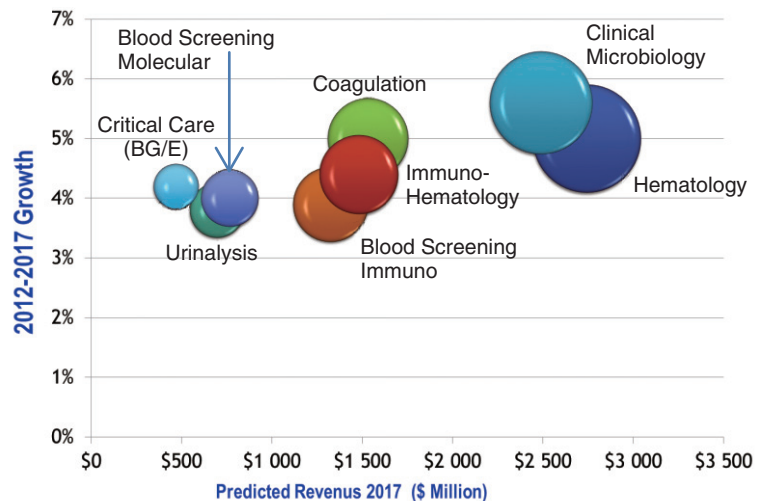


Figure 12 Expected revenue and its growth by segment (2012-2017)  
Source: Enterprise Analysis Corporation 2013

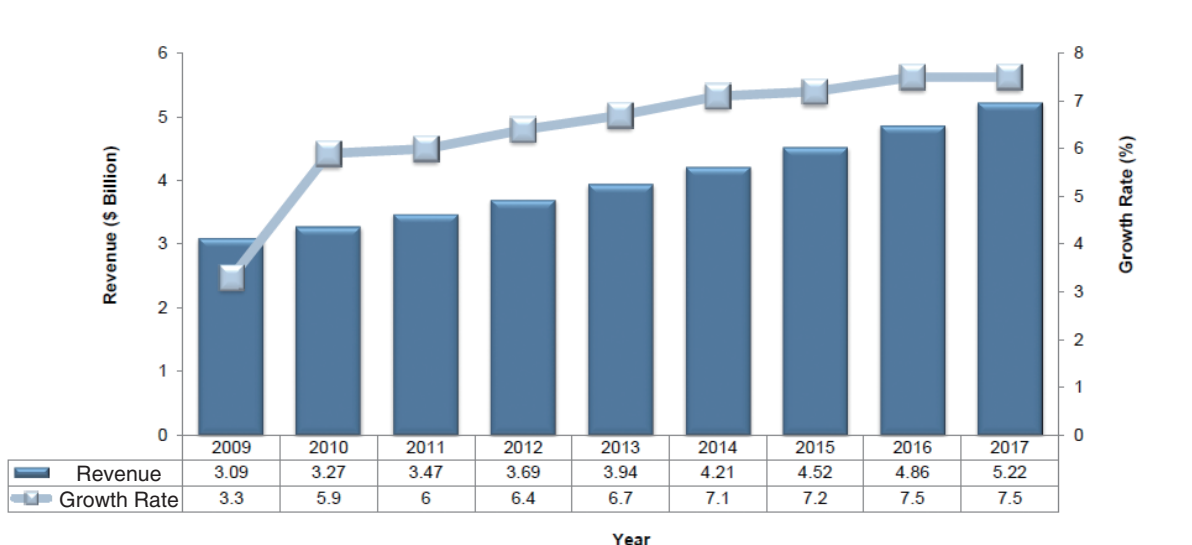


Figure 13 Hematology segment: world expected revenue and its growth (2009-2017)  
Source: Enterprise Analysis Corporation 2013

## The future of Central Laboratory and POCT<sup>\*6</sup>

The POCT can be defined as all acts of biology done outside the premises of laboratories of Medical Biology by untrained personnel and at the request of a physician (as mentioned in the "clearly segmented market paragraph). One of the major trends of IVD is the concomitant events of Labs Consolidation & Lack of trained technicians. The consequence of these events results in a high demand for large analyzers and automation in Core Labs in parallel with a strong demand for POCT.

The increased distance between the Core Lab and Point of Care and their TAT<sup>\*7</sup> is the consequence of the merger of middle size labs. These trends are stronger in developing countries than in the emerging countries. The demand for real POCT is growing at a fast pace for key critical care parameters (CBC, Cardiac Parameters, Electrolyte, Blood Gas, CRP.....) or for Disease Management parameters such as (HbA1c, Glucose). POCT is successful only if the physician has an interest to get the lab results at the same time of the visit, when he needs to make a therapeutic, or a Triage decision. For follow-up parameters like Cholesterol, Urea... the time to result is less urgent, and the interest of the POCT is reduced because of the higher cost/Test of the same tests performed in the Core Lab.

It is expected to encounter some change in the market structure to slowly move toward near patient testing due to reduction of cost and the need for a better turnaround time for results as shown on the table below.

\*6: POCT: Point of Care Testing

\*7: TAT: Turn around Time

## Conclusion

The hematology field is a very mature discipline where the quality of results provided by the existent technology is adequate for most clinical needs.

Hematology has achieved a steady state and, as for all other markets, to avoid the natural trend of price erosion it is necessary to find area of innovation. In addition, novel technologies and cutting-edge innovations in the biomedical and scientific fields still may influence and be applicable to hematology diagnostic testing.

HORIBA Medical's commitment is to be attentive to customer needs and provide solutions before those needs become requirements. In this sense our effort is focused on finding innovative services of pioneering biomedical researches such as Multiplexing, Micro-fluidics, Micro-arrays, Nano-particles, Magnetic particles, Piezo-electric sensors and Molecular diagnostic to improve and complete hematology results and diversify the approaches to diagnosis. Innovation does not necessarily require new technologies and it can be also expressed by ancillary solutions that have added value for customers and alleviate repetitive and prone-to-error tasks. Therefore improved connectivity as well as on-board data management is an area that can dramatically improve the quality conditions in a routine laboratory. Smartphone applications and wireless functions can greatly simplify the

diagnostic process and an provide quick disease follow up in rural or decentralized settings, such as home and self-testing. Traceability is becoming a requirement in healthcare all over the world. Handling complex databases (“the big data” as they are called) is the future. Therefore medical record storage and transmission seems to be the basic need of the new biomedical era.

Personalized medicine is a novel approach to therapy. Even if this strategy may have a strong economic interest in the pharmaceutical market it opens new niches of development and partnership between and pharmaceuticals and IVD. Indeed novel biomarkers and tests will need to be provided to prove and select the subpopulations adapted to specific therapies. HORIBA Medical knows that customer care passes through services and research in order to have diversified and adapted solutions that can impact future healthcare globally.

## Reference

[1] OECD (Organization for Economic Cooperation and Development)



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