French key sectors

In vitro diagnostics

Market segment dynamics

The in vitro diagnostics industry (IVD) develops and markets **devices and equipment (instrumentation and reagents) for carrying out medical analyses outside the human body (in vitro)**. These analyses are performed either in private laboratories and in hospitals, or to a lesser extent by patients themselves (home-tests).

In 2005, the world market for in vitro diagnostics was estimated at €25 billion. The European market shows a growth rate of 4.4%, and represents €7.8 billion (based on 13 European countries). Germany dominates this market with 25%, followed by France and Italy each with a market share of 19%.

France represents €1.5 billion, with a growth rate of 5.2%, which can be broken down as follows: 87% for reagents, 13% for instrumentation.

The IVD industry in France represents 196 companies (10,000 employees), more than 4,000 private laboratories (around 35,000 employees) and hospital laboratories. The splintered nature of this sector is specific to France, unlike Belgium or Germany which both work around large technical platforms and thus concentrate business around 200 players.

With regard to reagents, the distribution is dominated by biochemistry (32%) and immunochemistry (28%), followed by infectious immunology (16%), haematology (15%) and microbiology (7.6%). Genetic tests still only account for less than 1% of the market.

The highest growth rate is in blood sugar home tests (14.7%), linked both to the general increase in diabetic diseases and the implementation of patient selfmonitoring to optimize their treatment. Tumour markers and cardiac markers have shown the 2nd highest growth rate at 6%.

France's attractiveness

France's position from a global perspective is enhanced by its market and its positive image regarding research and innovation.

Regulatory control is an important factor for this industry. A European directive supervises IVD and is adapted to France. Marketing is the responsibility of the manufacturer, having obtained the "CE label" from an independent agency (LNE in France), which guarantees the quality of products. The AFFSAPS (the French health products safety agency) is the competent authority. Some products like those used in blood transfusion are subject to a special regulatory control.

The challenge today lies in integrating IVD as a whole into therapeutic strategy at the prevention, detection and therapy level, and monitoring the treatment progress.

Only doctors (GPs or hospital) prescribe medical analyses. Of the 360 million procedures in biology prescribed in 2004 and carried out by private laboratories, close to half were prescribed by general physicians. As part of the health expenditure control, some diseases are particularly supervised (diabetes and hepatitis C) while receiving the benefits of innovation in the IVD industry.

These innovations are in line with patient care strategy. The aim is to reduce the negative impact on private companies of health expenditure control measures which lead to a reduction in prices for private laboratories (reduction in rates of reimbursement and tariffs for the most commonly prescribed procedures), the implementation of the T2A in hospitals and the move towards a system of tendering for hospital purchasing.

In vitro diagnostics

International players in France

> **BioMérieux** (based in Marcy l'Etoile, in West Lyon) is a worldwide group specialized in the field of in vitro diagnostics intended for medical and industrial applications. It designs, develops, manufactures and markets systems used in the clinical and industrial fields. The in vitro diagnostics market covers several categories of technologies, four of which are at the heart of the BioMérieux business activity: bacteriology, immunoassays, haemostasis and molecular biology. Present in 150 countries, with more than 100 retailers and 35 subsidiaries, BioMérieux continues its international development.

BioMérieux is largely involved in the "Lyon Biopôle" cluster. This cluster aims to consolidate the current leading role worldwide of the Rhône-Alpes region in the fields of vaccines and diagnostics.

> **HORIBA** is an international company based in Kyoto, Japan, specialized in the design and manufacturing of analysis and measurement systems of liquids, gases and solids. France accounts for 24% of total HORIBA staff, which number 1,000 in the company's various subsidiaries.

The medical field represents one of the group's 4 main sectors of activity. This business, consolidated under the name HORIBA ABX, accounts for over 20% of its total business. ABX, a French company based in Montpellier, specializes in instrumentation for counting blood cells. In 1987, 5 years after the formation of ABX, HORIBA became its representative in Japan and signed a licence for sales and industrialization, which enabled HORIBA to make its first serious entry into the medical world. Through active exchanges, HORIBA started developing models based on ABX technology and products in Japan. In 1990, ABX became a part of the Swiss Hoffman-La Roche company. In 1996, HORIBA made it part of the HORIBA group. HORIBA ABX is now at the head of the medical division of HORIBA and is ranked 5th in the world.

Since 1819, Jobin Yvon has developed and manufactured instruments and components for the scientific field and has made significant contributions to technological progress in optical and instrumental spectroscopy at a global level. The main fields of application are: life sciences, optoelectronics, semi-conductors, pharmacy, environment and petrochemicals. HORIBA acquired Jobin Yvon in 1997; HORIBA JOBIN YVON SAS (Longjumeau) has since been a member of the HORIBA group.

> **Useful sites:**

www.sfrl.fr
www.lne.fr
www.afssaps-sante.fr
www.biomerieux.com
www.horiba.fr