France: Clinical Chemistry Market Brief

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Summary

Clinical chemistry is a dynamic sector in the French medical market. As the country struggles with the growing financial burdens of an aging population and a comprehensive national health care system, the necessity of leveraging the cost/benefit advantages of effective diagnostics is becoming more and more apparent. In-vitro diagnostics makes up the largest part of the market, and demand for self-test products is driven in particular by the growing number of diabetic patients in France as throughout Europe.

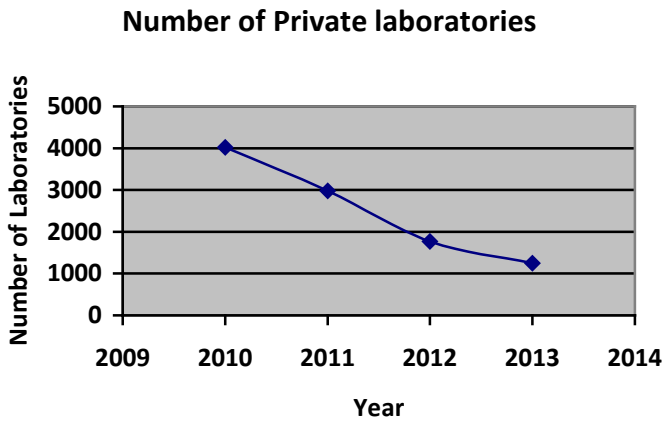
U.S. suppliers face a number of challenges in order to succeed in the French clinical chemistry market. The laboratory network in France is undergoing a process of restructuring and consolidation, though hospital and private laboratories are still the dominant consumers. Since these labs are reimbursed for a type of test, and not for a specific product, U.S. producers will have to compete heavily on price and quality to gain and retain these labs as customers. There are also regulatory challenges, such as compulsory CE marking and multilingual user manual requirements. Still, U.S. suppliers of clinical chemistry equipment and especially reagents should be able to find market opportunities in France. Hematology, bacteriology, molecular biology, genetic tests, and heart diagnostics are all projected as high growth areas.

Market Demand

France is the second largest clinical chemistry market in Europe, following just behind Germany. Sales were $2.34 billion, 16.8 percent of Europe's total. Like most countries, France's IVD (in vitro diagnostics or clinical chemistry) market is mostly for reagents, which account for 85 percent of total sales, as opposed to the remaining 15 percent accounted for by instruments.

The previous trend of growth in self-test products has been reversed in the past few years. This market sector shrank by 5.6 percent in 2012. However, the IVD sector has remained relatively stable, and within that, the market for reagents has grown. Due to the economic downturn in Europe and efforts by the government to curtail public spending, the market has diminished slightly in the past couple of years.

A market feature more particular to France is its continued reliance on its laboratory network for most clinical chemistry services. Consisting of over 6,100 biologists in over 2,149 laboratories (including 1,250 private laboratories), this network is the major consumer for the French clinical chemistry market. Currently, the industry is undergoing significant change, and is in the process of consolidating and regrouping laboratories. This has led to a rapidly shrinking number of biologists and laboratories, especially private laboratories, in the past few years. These changes are difficult at first, but should make the market more efficient in the long run.



Source: Syndicat de L'Industrie Du Diagnostic In Vitro SIDIV, (France's IVD Trade Association)

Market Data

An essential feature of the French IVD market is the way in which the country's health care system reimburses diagnostics. Unlike pharmaceuticals, the government's health product pricing committee generally does not assign specific prices to diagnostic tests. Rather, diagnostic tests are assigned a reimbursement percentage depending on the type of test, so the biologists in a hospital or a private laboratory can choose whatever brands of reagent that they wish to use for a given diagnostic. However, regardless of their choices, they will be reimbursed the percentage of cost predetermined for that kind of test. In general, the rates of reimbursement for France's public health insurance are as follows:

- Screenings for HIV or Hepatitis C are completely free for all patients
- Other laboratory analyses are reimbursed at 60-70 percent for most patients (private insurance will generally reimburse the remaining 30-40 percent)

The implications of such a system are straightforward: laboratory biologists have a clear incentive to choose the cheapest competing reagent for any given test. In theory quality should not be a consideration, since all reagents are guaranteed up to standards by virtue of their CE marking (see legal requirements). Therefore, suppliers must compete on price.

The major exception to this reimbursement scheme for IVD services is the reimbursement of diabetes monitoring products. These products are treated more as traditional pharmaceuticals in France. First, the government's Comité Economique des Produits de Santé (Pricing Committee for Health Products, known as CEPS) must price them. Then, in order for patients to be reimbursed for their over-the-counter purchases of these products, they must have a prescription from a physician. Patients can purchase these products without a prescription but they will not be reimbursed. The diabetic patient population in France is large and growing. Today there are nearly 3.5 million diabetic patients in France, and the figure is expected to double by 2020. The average yearly expenditure per diabetic patient for treatment is about $5,600.

Another important IVD market feature in France is that the country's private medical analysis laboratories are trending towards merging into larger units. Usually several private

laboratories join together as a Sociétés d'Exercise Liberal (liberal exercise company) known in France as a SEL. Within a SEL, each laboratory specializes in a specific type of analysis. There are about 1,250 private laboratories in France; many of them a part of a SEL as the laboratory network is undergoing restructuring and consolidation. Being part of a SEL means that an individual laboratory will need far less equipment in total, because they will only have needs for their particular specialization. However, within that specialization, laboratories will need far more of their particular reagents, and will buy much bigger models of their specialized equipment in order to handle the increased load. This change in demand should be good for suppliers to the French IVD market, but suppliers should also bear in mind that by banding together these SELs will have much greater purchasing power than individual labs did before.

A far more recent market development is the system-wide reform currently underway in the French health care program. In an effort to cut costs while maintaining quality, the French government is instituting what is known in the United States as DRG or Diagnosis Related Groups, referred to in France as T2A. The principle of the reform is to tie reimbursements (and therefore costs), to a particular diagnosis. So if a patient is diagnosed with diabetes, they are allotted so much for treatment, so much for monitoring, so much for transportation. The program was fully instated in 2007, and its long-term repercussions have yet to be seen. Industry insiders fear that at first the reforms may hurt the market, depressing demand as other medical services compete for reimbursements. However, the French IVD industry hopes that in the long run the government will recognize the cost saving advantages of IVD investments. They believe that leveraging those savings can be a part of successful reform efforts.

A final salient aspect of the French IVD market is the general absence of what is known in the United States as the point-of-care market. By law French general practitioners cannot execute most diagnostic tests themselves. Instead, French biologists in laboratory settings must perform these tasks. The main exceptions to this rule are tests for angina and tests performed in emergency rooms or at hospital bedsides. Nevertheless, there are potential consumers in France for equipment that is designed for the U.S. point-of-care market. Automated equipment that is used in the United States by a small group of doctors doing point-of-care diagnostics can handle the same workload as that faced by small laboratories in France. Therefore these small laboratories are logical consumers of certain equipment that was designed for the point-of-care market in the United States.

Always a large importer, France has also traditionally been a strong exporter of IVD products. However, in recent years import growth has outpaced export growth, as export growth has stagnated. This trend may stem from the fact that the passage of the standardized CE regulations has made it harder to fend off foreign competition through regulatory maneuvers. U.S. imports into France generally account for nearly 45 percent of total imports.

French IVD Market Overview

	2010	2011	2012
Total imports	878	925	972
Total exports	819	862	905
Local production	1,606	1,691	1,777
Total market size	1,665	1,754	1,844
Imports from U.S.	395	410	434

(Figures in $millions; estimates from combined data sources)

Best Prospects

Laboratory Equipment Market Trends and Features

French laboratory equipment buyers are discriminating and demand high quality. Key buying factors include reliability, durability, and state-of-the-art technology. An important new trend is towards ergonomically-designed equipment.

The degree of product automation, which improves the precision, accuracy, and speed of the measurements and analyses, is another major consideration. Another industry trend is the increasing integration of laboratory equipment and computers. Data can thus be transferred quickly and accurately between different instruments, enabling an optimal interface between end-users and their equipment.

In some cases, producers of very expensive equipment make their products available at a minimal charge, and generate income from the subsequent sales of reagents and consumable supplies. For the laboratory share of the clinical chemistry market the highest growth is predicted in the hematology, bacteriology, molecular biology, genetic tests, and heart diagnostic sectors. The market for reagents has continued to grow in the past few years, despite a slight overall market decline.

In 2012, market share values of reagent segments in France were as follows:

Product Segment	Percent of Sales in 2012
Biochemistry	10%
Immuno-Chemistry	37%
Infectious Immunology	19%
Hematology	21%
Microbiology	11%
Genetic Testing	2%

Health Data- France

As of the beginning of 2013, France counted a total population of 63.7 million people. Effectively 100 percent of this population has access to quality healthcare through some combination of public and/or private insurance. The country's healthcare infrastructure is extensive, comprising nearly 1,000 public hospitals, over 110,000 doctor's offices and around 20,000 pharmacies. The primary financial support for this infrastructure and its services is highly centralized. In the end, France's national health care program, known as Social Security, pays roughly 75 percent of all health care costs. Private insurance companies in France cover an additional 20 percent of the total costs. This leaves very few health care costs to be paid by individuals themselves, and thus creates significant incentives for consumption of health services.

These incentives lead directly to a healthy annual growth rate of six percent or more for French health care consumption. The country saw some $3,974 spent on health care per inhabitant in 2012. Of that amount, about 1.8 percent of total health spending is for clinical testing.

Another salient feature of France's national health is its aging population. The percentage of the French population aged 65 or older reached nearly 18 percent in 2012. After that, projections show this percentage continuing to grow, perhaps reaching 27 percent by 2040. This demographic maturation is expected to accelerate the country's current challenges of

growing patient populations for diabetes and cardiovascular diseases. Given this trend, the cost/benefit features of effective in vitro diagnostics will become increasingly essential to the French national health care program, as it faces ever-heavier burdens.

Structure by Age of the French Population

Year	Under 20 yrs old	20-64 Yrs Old	> 65 Yrs Old
1985	29.2%	58.0%	12.8%
1995	26.1%	58.9%	15.0%
2005	25.2%	58.6%	16.2%
2012	24.7%	57.9%	17.5%

Key Suppliers

Domestic Production

Domestic production comes from both French-owned companies and subsidiaries of multinational corporations. The industry within France employs nearly 10,000 workers. Companies that actually produce their products in France include bioMérieux, Diagnostica Stago, Diamed, along with foreign investors such as Becton Dickinson (U.S.), Bio-Rad (U.S.) and Horiba- ABX (Japan). It is notable that the top three French companies (bioMérieux, Diagnostica Stago, and Diamed) are much stronger in France than they are in the European Union as a whole, or on the world market.

Third Country Imports

The French IVD marketplace is truly global. In order to capitalize on comparative trade advantages, major players often produce large equipment components in several different countries, and assemble the machines in a third country. As a result, the origin of certain medical equipment is difficult to pinpoint. Approximately 50 percent of IVD equipment and reagents used in France is imported, most coming come from the United States. The second largest exporter to France is Switzerland (Roche Diagnostics) Germany (Siemens-Bayer Diagnostics DPC). The French market is easily accessible for foreign products. The high import percentage indicates that purchasers give priority to the quality and benefits of a product over the country of origin.

U.S. Market Position

Success of American companies in this market is based on high quality, innovative technology and comprehensive after-sales service. To achieve these ends, American firms dedicate a high proportion of their earnings to research and development. Feedback from biologists, purchasing agents, hospitals, etc., is constantly integrated into product design. The strong reputation of American products within this industry is reinforced by French trade journals.

The main subsidiaries of American companies that are active in the IVD market in France are: Abbott, Johnson & Johnson, Beckman Coulter, Dade Behring, Bio-Rad, and Becton Dickinson.

Prospective Buyers

User Groups in the IVD market in France come from the following segments: private laboratories, hospital laboratories (private and public), EFS (Etablissements Français du Sang or blood banks) and other (includes over-the-counter (OTC) or self-test market). The majority of IVD tests will definitely continue to remain in the hospital and private laboratory setting. However, this dominance will weaken slightly as the OTC market grows.

The most recent trend affecting the French clinical chemistry market is the consolidation of laboratories. The overall number of laboratories declined by 21 percent from July 2012 to July 2013. The largest decline was among private laboratories, the numbers of which declined by 29 percent during the same period. This decline was balanced by growth in laboratories in public and private hospitals.

Despite this change, the dominant consumer in the French IVD market will continue to be laboratories. They are so numerous and so ingrained in the way French doctors and hospitals go about their work that this dominance is predictable for the foreseeable future. Laboratories are generally either a part of a public hospital, or a private lab outside of a hospital. Although some private hospitals also have their own laboratories, most contract with a private laboratory or laboratories. These arrangements generally create a relationship of cooperation between laboratories and private hospitals.

Laboratories in France

Private Laboratories	1,249
Hospital Laboratories	769
Blood Bank Laboratories	138
Cancer Research Center Laboratories	27
Military Hospital Laboratories	13

Source: Syndicat de L'Industrie Du Diagnostic In Vitro (SIDIV, France's IVD Trade Association)

Market Entry

There are three main ways for U.S. firms to sell IVD products in France: through an agent, using a distributor or by establishing a subsidiary. Exporting through a distributor or agent is the most common practice.

An agent works with retailers and end-users to promote the company's products. An agent's commission for scientific laboratory equipment is usually about 15 to 20 percent, and agents will frequently request exclusive representation. Agents are protected by a number of laws in France. If a U.S. manufacturer of IVD products wishes to terminate his business relationship with his agent prior to the expiration of the contract, the agent must first be contacted and given the opportunity to improve his performance. If the U.S. manufacturer still wishes to end the relationship after these steps have been followed, the agent has the right to retain the names of all contacts, clients, and related sales information. The manufacturer may purchase this information from the agent, but it is often very expensive. Lastly, the manufacturer could often owe the agent a severance payment ranging from one to two years of the agent's anticipated future commissions.

A distributor purchases products from the U.S. manufacturer, then adds a 30 to as much as a 50 percent markup to cover commissions, credit risk, after-sales service, and the cost of carrying a local inventory to meet small orders. The distributor normally pays Value Added

Tax (VAT) and tariffs. French distributors also often request exclusive contracts. Many U.S. companies use a distributor when introducing a product that employs a new technology or design. The distributor shares much of the same legal protection as the agent. If termination occurs prior to contract expiration, the usual termination equals the value of the distributor's expected profit margin over a two-year period. Furthermore, an IVD products distributor representing a U.S. product in France controls the product's marketing strategy and image. The distributor is also not obligated to communicate market research information to the U.S. manufacturer. It is therefore important to select a distributor who is completely in tune with the U.S. company's goals and objectives.

Establishing a subsidiary offers several advantages to the manufacturer: more control over their distribution practices, the ability to adapt quickly to evolving needs of the market, more direct influence over the training of personnel, and control over unauthorized dissemination of technology for which the U.S. firm holds a patent. However, a subsidiary involves a much greater financial investment and the responsibility of maintaining assets and employees in a foreign country.

Small and mid-size companies will likely find that a distributor will provide the fastest way to break into the market. Distributors are on the ground, have a set stable of products that bring them into regular contact with target customers, and know how to promote these products locally.

Promotion of these items normally occurs at trade shows and in the specialized media delineated below. Note that since doctors cannot themselves administer these diagnostic tests, marketing directly to doctors is of no use.

Market Issues and Obstacles

Legal Requirements

As of December 7, 2005, the EU-Directive (98/79/EG) on In-Vitro Diagnostics requires that all IVD products, including accessories, have CE marking. Other certifications are not necessary and not allowed. The CE marking is an administrative and quality symbol for IVD products recognized worldwide in the interest of facilitating trade and denotes that the IVD product has passed the required conformity assessment procedures and that it satisfies all regulations. In particular, the CE marking papers document performance of the risk analysis and satisfaction of all “Basic Requirements,” with the use of state-of-the-art technology. France, in particular, spearheaded the stringency of the EU-wide requirements.

The IVD Directive divides in-vitro diagnostics into two categories, high risk and low risk. IVD products constituting a high risk and self-test products have to be certified by a so-called “Notified Body.” The only French notified body is the Groupement Pour L’Evaluation Des Dispositifs Medicaux (Medical Product Evaluation Group, known as GMED).

With high-risk products, the Notified Body also examines product design and batch release. With low-risk products, the manufacturer declares at his own responsibility that his products are in conformity with the requirements of the law. This declaration includes confirmation of a quality assurance program in place. In all cases, the manufacturer or the distributor (where the manufacturer has no presence in France) is subject to control by the responsible regional authority.

The responsible regional authority for France is its equivalent of the U.S. FDA, called the Agence Francais de Securite Sanitaire des Produits de Sante (French Health Products Safety Agency, known as AFSSAPS). Although this agency does not directly approve or monitor IVD products in France, it should still be of concern to IVD suppliers. All laboratories in France are subjects to AFSSAPS inspection, and therefore so, too, are the IVD products and equipment within those labs. Laboratory purchasers will no doubt be aware of this fact when making their decisions. Diagnostic tests that will be reimbursed through the public insurance system in France also have to be priced by the government's Comité Economique des Produits de Santé (Pricing Committee for Health Products, known as CEPS).

Tariffs, Import Regulations and Taxes

Official trade barriers, such as quotas, do not exist. Both diagnostic instruments (HS Code 9018199000) and diagnostic reagents (HS Code 30063000) are duty-free. However, France does apply two specific taxes to the IVD industry. First, manufacturers selling into the in-vitro diagnostic market in France must pay 0.24 percent of their sales before tax, so as to fund the Agence Francais de Securite Sanitaire des Produits de Sante (French Health Products Safety Agency, known as AFSSAPS). Second, there is a 10 percent tax on any promotional spending on enterprises supplying diabetic patients with self-testing material for glycaemia (Law N 2004-810 relative to health insurance).

Trade Events

Name of event: Journées Internationales de Biologie - JIB
Location: PARIS / C.N.I.T. La Défense
Date: Nov. 13-15, 2013
Website: http://www.jib-sdbio.fr

Description: Laboratory Equipment and Supplies Exhibition. It is an annual event. With 177 exhibitors, an area of over 4,300 square meters, 7,957 visitors, JIB is the largest medical laboratory trade show in France.

Resources

For More Information

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