

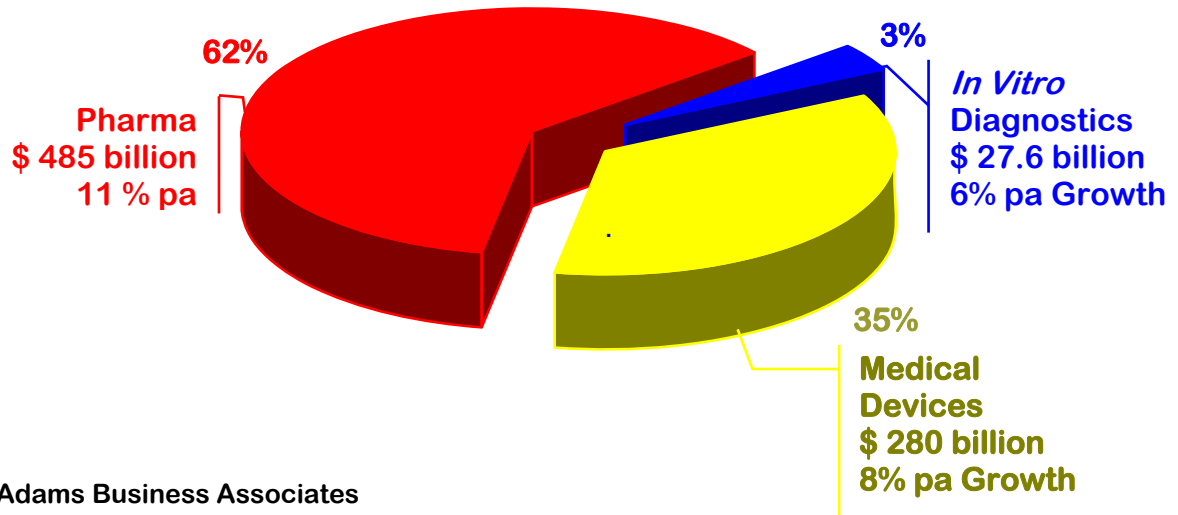


Market Review of the Global Diagnostics Market for DiagnOx, February 2005.

The following review of the global Diagnostic market has been prepared by Adams Business Associates as a member of **DiagnOx** to provide the core market information for the business sector covered by **DiagnOx**. It is an essential feature of the Technology Transfer process from research to commercial development that there is an understanding of the possible markets. This knowledge should not be limited to knowing where the technology can be used but extended to competing options already in use and the broad context of healthcare.

Diagnostic products are now being much better appreciated as important tools in reducing costs to the healthcare systems in all countries. In the past, Diagnostic tests were used mainly as support data for the real diagnosis, often being used to confirm the physical diagnosis of the doctor or for legal protection that the correct procedures had been carried out. Use in monitoring response to treatment did become an established use of Diagnostic tests and this remains an important part of current practice. A major change over the last decade has been increased use in true diagnosis and differentiation of conditions in order to achieve the best treatment. The driving force for this shift in role for Diagnostic tests has been the large costs for healthcare throughout the world at a time when the economies have been less robust.

The focus on reducing healthcare costs at a time of increased patient demand has been on the three main product sectors of **Pharmaceuticals**, **Medical Devices** and ***In Vitro* Diagnostics**. The markets for these products in 2004, **Figure 1**, added up to nearly one thousand billion dollars world wide (\$ 800 billion) with Diagnostics the small partner (3%) of the trio. It is now being increasingly recognised that thoughtful use of this smaller partner can lead to savings in the costs for the larger Pharmaceutical and Device products as well as providing significant savings in other costs for healthcare treatment, such as reduced time in hospital in-patient treatment.

Figure 1. Global Healthcare Markets, 2004.**Total = \$ 793 Billion**

Source: Adams Business Associates

The attraction of investing in the development of Diagnostic products has been boosted by this change in importance and the recognition that the overall risks are reduced together with an earlier return on modest investments. The costs, acceptable sales targets for success and the time scale for commercialisation are summarised in **Figure 2**.

Figure 2. Costs to Market and Benchmark Success levels, 2004.

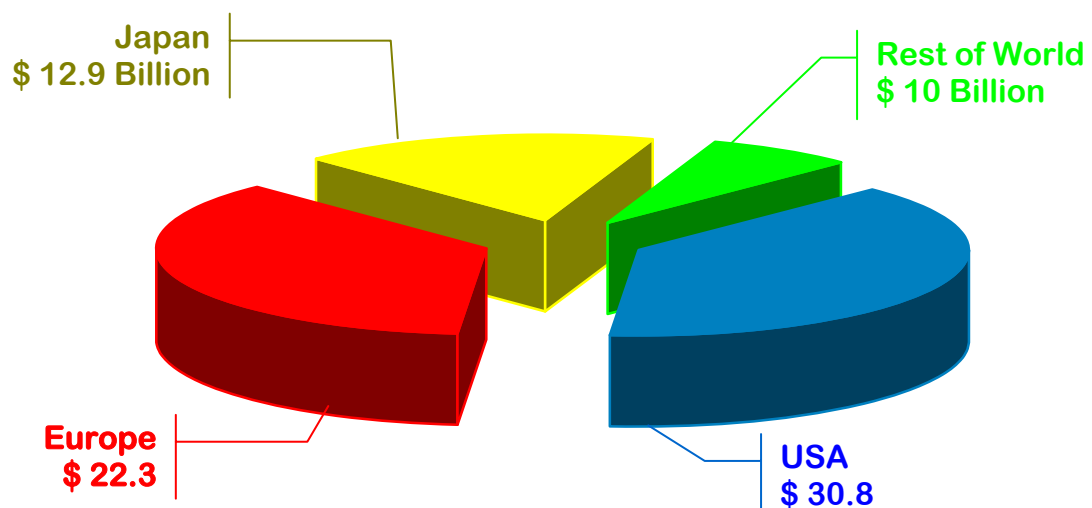
Feature	Pharma	Medical Device	Diagnostic
Average Cost to Market	£ 900 Million	£ 250 Million	£ 2-10 Million
Major Product Revenue Mark	£ 1 Billion	£ 50 Million	£ 20 Million
Years to Market	6 – 15 years	3 – 5 years	1 – 3 years
Net Profit Level	10 –15 %	5 -10%	10 – 25%

Source: Adams Business Associates

There are many types of Diagnostic product, with special devices attached to the patient used for Patient Monitoring and Imaging agents used to study organ function or locate cancers, as examples. In 2004 the total market for all these products, **Figure 3**, was almost eighty billion dollars (\$ 76 billion) distributed by region as shown.

Figure 3. Global Diagnostic Market Distribution by Region, 2004.

Total = \$ 76.0 Billion.



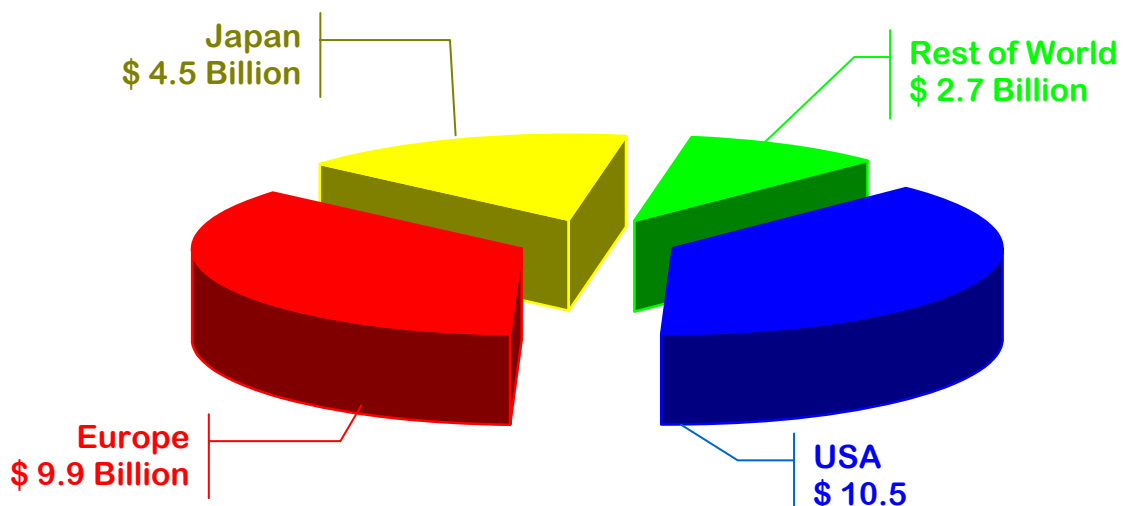
The *in vitro* Diagnostics (IVD) sector is concerned with tests that are carried out on a patient sample, not necessarily in a laboratory, with self-testing for glucose by diabetics the major non-laboratory example. The overall IVD market has modest growth (about 6% per year) but there are new developments where much higher growth has been seen in recent years. The main areas of above average growth identified in the 2003 report from the European Diagnostic Manufacturers Association (EDMA, see www.edma-ivd.be) were:

Glucose Tests	> 10%
Cardiac Tests	> 20%
Nucleic acid Based Tests	> 20%
Genetic testing	>> 20%, but from a small base

The global distribution for all IVD products is shown in **Figure 4**, with the markets of the USA (38%) and Europe (36%) accounting for almost three quarters (74%) of the total market in 2004. It is expected that although currently a small part of the global market there will be much faster growth in the developing country markets. These countries often have special diagnostic problems, such as those related to tropical diseases and infections, but all seem to be showing the same trends toward “western” conditions with Diabetes, Cardiovascular Disease and Cancer all increasing.

Figure 4. Global IVD Market Distribution by Region, 2004.

Total = \$ 27.6 Billion.



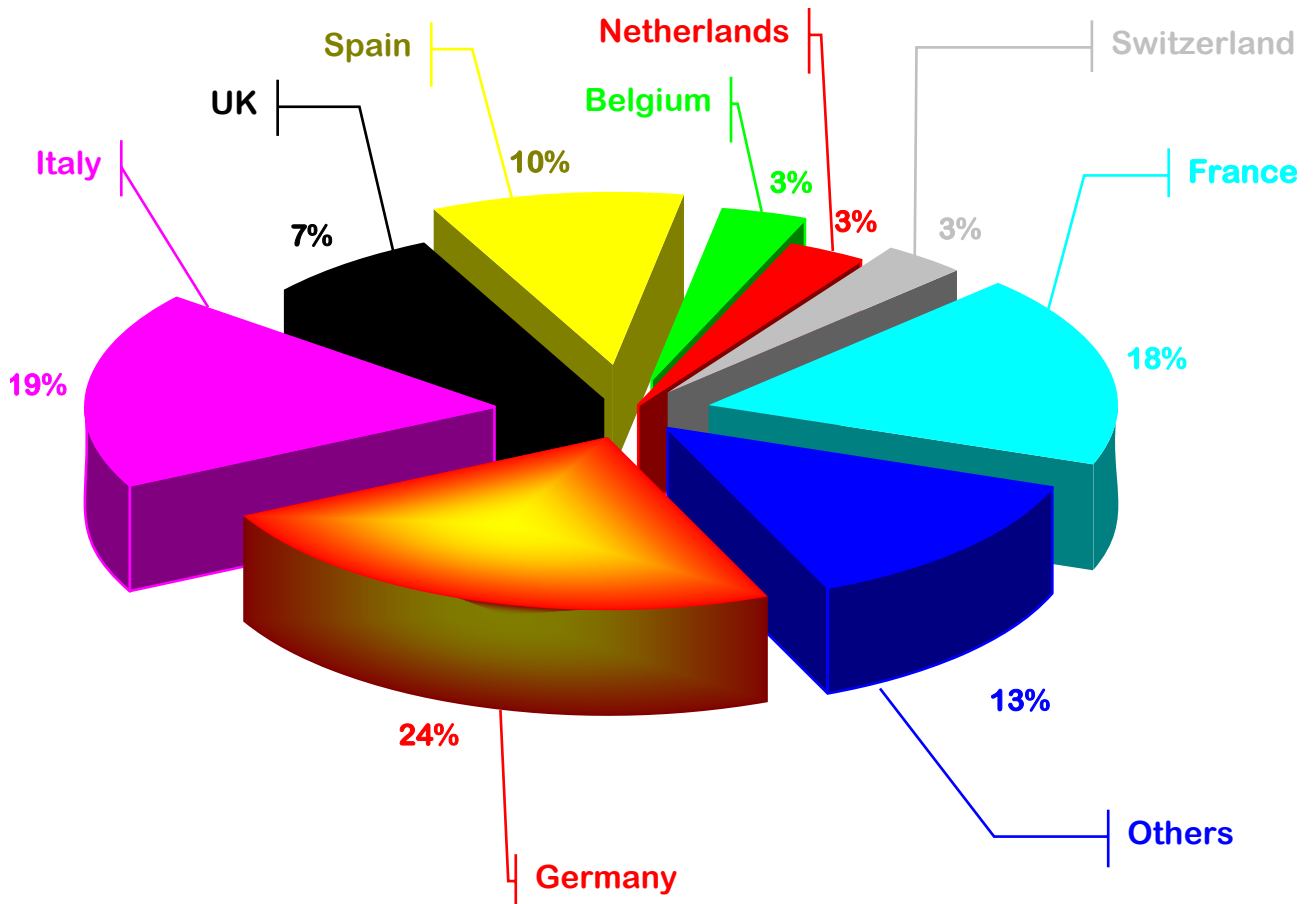
The distribution of the IVD reagent market within the European countries is defined from the EDMA market report based on its survey carried out from data supplied by its members. This analysis is summarised in **Figure 5** below.

The conclusion is that the Diagnostic market is growing in importance with new clinical areas that can be exploited and opportunity for new technologies to open up new markets. It is important to recognise that as in all areas of healthcare the Diagnostic market is a global business and activities in all regions have to be taken into account in commercialising technology innovation.



Figure 5. Distribution of IVD Market in Europe, 2003.

Total Market Value = \$ 9.9 billion [Euros 8 billion]



Source: Adams Business Associates based on EDMA

Others are:
Austria
Finland
Greece
Poland
Portugal
Romania