



“ Making a Real Difference in Health & Life Quality ”



European Diagnostic Manufacturers Association

## ABOUT

### ABOUT EDMA

EDMA, the European Diagnostic Manufacturers Association is the trade association that represents the *In Vitro* Diagnostic (IVD) industry active in Europe.

EDMA membership brings together National Associations in European countries and the major companies engaged in the research, development, manufacture or distribution of IVD products. Through its affiliated National Associations, EDMA represents in total more than 500 companies (or over 700 legal entities) across Europe.

Since its establishment in 1979, EDMA acts in co-operation with other European and international trade associations representing medical devices, pharmaceuticals and biotechnology in general, as well as with public authorities, scientific societies and patients organisations to make a real difference in health and life quality.

### ■ The Value of In Vitro Diagnostics

The IVD industry manufactures biological and chemical reagents, automated machines and devices that are used for the medical analysis of body fluids. Among health professionals, these tests are called *In Vitro* Diagnostics because they were originally performed in glass test tubes (*In Vitro* means literally "in glass").

Tests performed on samples (e.g. blood, tissues, saliva, faeces or urine) taken from the body are

a unique source of objective information about the body and how it functions. This information is vitally important for clinical decision making: **IVDs information influences about 64% of the medical decisions** (JD. Kruse-Jarrest, *Lab. Med.* 18:213/1994).

**64% of the decisions taken by doctors are influenced by diagnostic tests results**

Laboratory testing has indeed an essential part to play in the healthcare chain. From the prevention and diagnosis, in the broad sense, which takes into account the predisposition and the precise determination of the disease and its severity; to the monitoring of treatment, allowing assessment of its efficacy and its adjustment; disease management in the case of chronic pathologies; and confirmation of therapy efficacy to rule out any risk for persistence of disease.

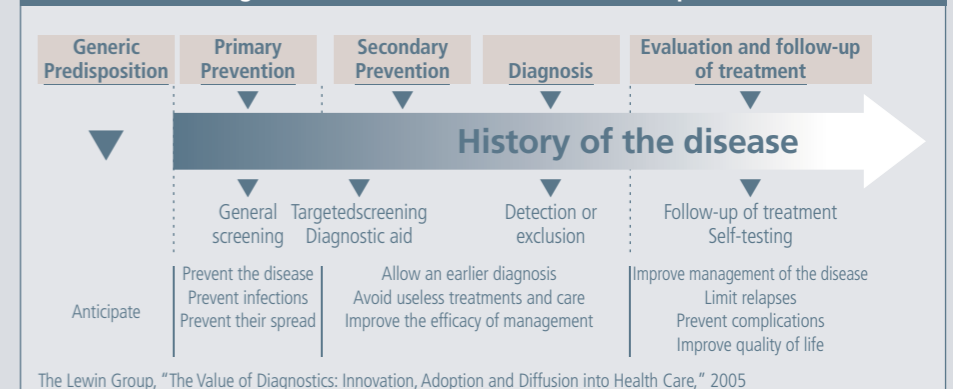
2%  
of European  
Healthcare  
Expenditure

Influences  
64%  
of medical decisions

According to the EDMA 2006 European Market Estimates, the average IVD industry sales represent in the majority of EU countries **less than 2% of the Total Healthcare Expenditure**. An appropriate and rational use of *In Vitro* Diagnostics would allow European health and the national systems to improve the quality and the economics of the service they offer to the citizens.

A rational allocation of resources to diagnostics would improve the quality and economic sustainability of European healthcare systems

### *In Vitro* Diagnostic tests: an essential role at each step of the disease



The Lewin Group, "The Value of Diagnostics: Innovation, Adoption and Diffusion into Health Care," 2005



Making a Real Difference in Health & Life Quality



## IVDs

### ■ EDMA Mission & Strategy

EDMA **mission** includes the following spheres of activities:

- to promote the value of *In Vitro* testing and to raise awareness of the importance, usefulness and added-value that diagnostic information provides to healthcare;
- to support an appropriate regulatory system,
- to work towards a realistic economic environment for healthcare in Europe in order to ensure the continued supply of high quality, cost effective products, and
- to be an effective voice in globalisation.

Targeting the previous objectives, EDMA **strategy** is to promote the value of laboratory testing in healthcare, showcasing the essential contribution that numerous IVD technologies can offer to prevention policies and disease management, and creating objective sources of information on laboratory testing available to the European citizens in general.

The Association also works to improve economic conditions in the market for IVD products both in Europe and world-wide. For this purpose, EDMA supports the implementation of the Single Market and advocates a regulatory system in Europe that is appropriate to the risks involved, assures high quality healthcare and protects the interests and safety of patients.

EDMA encourages evidence-based medical practices as a basis for effective healthcare,

supports the trend towards integrated disease management and promotes the concept of greater individual responsibility for health management.

Industry requires a realistic healthcare environment, which provides a stimulating climate for scientific and technological innovation, in conditions conducive to long term and international competitiveness.

### WHAT EXACTLY ARE IVDs?

According to the **European IVD Directive (98/79/EC)**, 'In Vitro Diagnostic' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination. These elements will be intended by the manufacturer to be used *In Vitro* for the examination of specimens derived from the human body, solely or principally for the purpose of providing information concerning a physiological or pathological state or a congenital abnormality, to determine the safety and compatibility with potential recipients, or to monitor therapeutic measures.

IVD testing includes measuring the concentrations of various chemical and biochemical components, counting cells, measuring physical properties of the sample, microscopic examination of cells and other structures or making biological cultures. Most diagnostics are used in the **laboratory**

setting. User-friendly devices can also be used by medical professionals (**Point-of-Care testing**) or by the patients themselves at home (**Self-testing**).

### ■ Multiple roles in protecting health

Diagnostics contribute to several instants of the healthcare chain:

#### • Population screening and disease prevention

*In Vitro* tests are widely used in prevention of disease, for example, to screen populations or groups for hidden disease or risk factors. *In Vitro* tests inform about predisposition to disease through genetic testing, and also assist in preventing spread of infection, e.g. via the blood supply. IVDs information helps establishing the state of health of individuals, as well as to indicate the state of health of the general population as a whole. In a time where **prevention** is recognised as the key factor to protect health and reduce the healthcare burden, the role of IVDs cannot be underestimated.

#### • Diagnosis

Early and correct diagnosis is a prerequisite for effective treatment. Early detection or diagnosis generally leads to early and effective treatment that saves costs to healthcare systems in the longer term. One of the first steps after a medical examination is often to take a blood sample and to request the medical laboratory to carry out a number of *In Vitro* tests.

• **Monitoring of treatment prescribed**

*In Vitro* tests help in evaluating the patient's condition and evolution during therapy; allowing to reassess and update the treatment. IVDs can also be used in the monitoring and management of therapies and chronic diseases (theranostics), e.g. blood glucose self-testing control in diabetes, -determining susceptibility to antibiotics, therapeutic drug monitoring in immunosuppression, etc. Also, using biochemical parameters ensures that treatment given is having the required effect and is therefore appropriate and effective, which usually has a positive impact in therapy compliance.

• **Assessment of medical interventions**

As resources available to public health systems are limited, medical interventions are increasingly subject to Health Technology Assessment (HTA). *In Vitro* testing is often an essential part in these assessments.

• **Other (non-medical) applications of *In Vitro* testing**

These include essentially the production processes of the medicinal industry (ensuring that pooled blood for plasma protein production does not contain viruses); the veterinary medicine; the environmental control (water quality, soil analysis); and the food industry for the detection of contamination or presence of micro-organisms (bacteria, viruses, fungi) in food or raw materials (e.g. penicillin in milk).

■ **Inventing the Future: Technology Convergence and Personalised Medicine**

New systems developed by the electronic industry have enabled the miniaturisation of biosensors used in IVD tests. These new techniques, known as **nano-diagnostics** ("Biochips", "Lab-on-a-chip") will incorporate several analytical tests and allow in the future providing a full medical diagnosis from a single sample.

Close cooperation between diagnosis and intervention will result in vast pharmacogenetic know-how, translating individual metabolic fingerprints for use in **personalised medicine**, tailored to individual needs. The goal is not only to match proper diagnosis with right treatment, but to predict which drug and dosage will work best for each patient.

It is foreseeable, that new, more specific and much more expensive methods of treatment – such as in the case of patients with cancer and other severe diseases – will require highly specific diagnosis, in order to guarantee successful and affordable therapies. Combined techniques between diagnostics and therapies, **theranostics** could be one of the major healthcare tools in the future. Nano-particles carrying therapeutic agents into disease cells will check for over-dosage before becoming active, thus preventing drug-related poisoning.

As a result, life span will increase, based on improved diagnosis of predispositions and the possibility to affect gene therapy.

■ **Making the difference**

As new frameworks for patient care emerge, *In Vitro* Diagnostics hold the key to implementation and the opportunity to provide cost-effective public health service in Europe and worldwide. For the patients, a return to health often depends on correct and early diagnosis and on monitoring of the treatment provided.

**The role of IVDs needs to be recognised and adequately funded to pave the way for fully realising their potential benefits in both clinical and financial terms**

Highly automated, IVD testing provides valuable data at low cost, thus allowing global healthcare savings while contributing to increase its quality. IVDs allow earlier and more appropriate treatments, thus helping to shorten length of hospital stays, rule out expensive treatments and reduce costs of treatment of complications. Moreover they assist to keep under control the spread of infectious diseases in the community. Diagnostics are non-invasive, thus procuring the patients' safety and comfortability.

Incorrect diagnosis leads to inappropriate and expensive treatments, while failure to diagnose allows the untreated progression of disease.

The IVD industry thus plays a vital role in the public health sector **providing patients benefits, clinical benefits and economic benefits**; a valuable contribution EDMA is committed to communicate and promote.

**Classification of IVDs by category of reagents**

**Clinical Chemistry**

Clinical chemistry tests are usually grouped in panels and routinely ordered to determine a person's general health status. They help evaluate the body's electrolyte balance and/or the status of several major body organs. The tests are performed on a blood sample, usually drawn from a vein in the arm. They are mostly referred to as the basic or comprehensive metabolic panels, the liver panel, the electrolyte panel, the lipid profile, etc.

**Immunochemistry**

The large array of *In Vitro* diagnostic tests gathered under Immunochemistry tests are based on antigen-antibody reactions. They can be sub-categorized into various sub-specialties, including:

- Plasma Protein dosage
- Endocrinology: hormone level dosages permitting to evaluate the thyroid function to define fertility levels, determine pregnancy, etc.
- Allergy and auto-immune disease tests
- Anaemia determination
- Oncology: Tumor Marker tests allow to identify various cancers
- Therapeutic Drug Monitoring and Drugs of Abuse testing

**Haematology**

Under this category, one can find a variety of tests from basic Blood Typing tests to Tissue Typing; Blood Cell Counts to measure the number, type and size of red and white cells; as well as platelets but also Coagulation tests, which are key before a surgical intervention, for instance. General Histology tests can also be found under this category.

**Microbiology**

The multidisciplinary science of micro-organisms. The prefix 'Micro'

generally refers to an object sufficiently small that a microscope is required for visualisation. Bacteriology, as a precursor science to microbiology, was based on Louis Pasteur's pioneering studies in the 19th Century, when it was demonstrated that microbes as minute simple living organisms were an integral part of the biosphere involved in fermentation and disease. Microbiology matured into a scientific discipline when students of Pasteur, Robert Koch and others sustained microbes on various organic substrates and determined that microbes caused chemical changes in the basal nutrients to derive energy for growth. Modern Microbiology continued to evolve by encompassing the identification, classification and study of the structure and function of a wide range of micro-organisms including algae, fungi, viruses and parasites as well as bacteria.

The EDMA classification distinguishes between:

- Microbiology: laboratory systems allowing the culture and identification of micro-organisms, and
- Infectious Immunology: a broader range of tests allowing the diagnosis of Hepatitis and Aids but also the identification of many other viruses, like Rubella, Measles, Herpes and CMV; or bacteria like Chlamydia and Mycobacterium; and even parasites like Toxoplasmosis.

**Genetic Testing**

This revolutionary discipline analyses *In Vitro* structural properties of deoxyribonucleic acid (DNA), sequence and/or chemical modifications of nucleotides, as well as of those properties of ribonucleic acid (RNA), proteins or metabolites that are the direct and sole consequence of their DNA template structure. By doing this, the goal is to provide information about inherited or acquired traits that are transmitted during cell division and that affect all subsequent generations of cells (somatic) or offspring (germinal). These tests are widely used in parenthood determination or police investigations.



### EDMA ACTIVITIES

Correct and early diagnosis is key to effective healthcare in the long term. An incorrect diagnosis and unnecessary or wrong treatment will lead to excessive healthcare costs. EDMA has therefore reinforced its **communication and public affairs activities**. The main challenge is to communicate EDMA commitment to Public Health, and to present laboratory testing as a valuable asset that is a cost-effective component of health maintenance and disease management.

Strengthened contacts with all healthcare stakeholders are key to establish new spheres of dialogue for the identification of synergies, the definition of new innovative solutions and the joint and successful implementation of consensus propositions in Public Health. The overall aim is to ensure that healthcare resources are properly allocated and appropriately used to ensure successful healthcare systems across Europe. Laboratory testing has an important role to play in achieving this aim.

Since its creation in 1979, the particular interaction with the **regulatory environment** has always been one of the core activities of EDMA. For the European IVD industry to be competitive and to ensure that it can deliver to the medical professionals state-of-the-art diagnostic tools which can be used to safeguard the health of European citizens, both individually and collectively, the regulatory environment needs to be tuned to the needs of all those involved: regulators, healthcare professionals, patients and industry.

At the European, and increasingly the international level, it is the role of EDMA to represent the *In Vitro Diagnostic industry* in its discussions with other stakeholders, aiming at working together towards an appropriate regulatory environment.

**Market Research** is also an important sphere of activity for EDMA, committed to maintaining and building market statistics and a classification system for IVD products. The Consolidated

Market Statistics published annually by the Association are one of the best tools available to understand the trends in our industry.

### CONTACT US

For more information about EDMA and the *In Vitro Diagnostic* sector, visit our website on [www.edma-ivd.be](http://www.edma-ivd.be) or contact our Secretariat at:

Place des Maïeurs 2  
B-1150 Brussels  
Tel: +32 2 772 2225  
Fax: +32 2 772 2329  
e-Mail: [secretariat@edma-ivd.be](mailto:secretariat@edma-ivd.be)