

THE CZECH MARKET WITH IN VITRO DIAGNOSTIC  
MEDICAL DEVICES



**Motto: „Finances used in relation to IVD are not costs but true investments in health“.**



Czech Association of In Vitro Diagnostic Medical Suppliers  
Na Ořechovce 58, 162 00 Praha 6  
[www.czedma.cz](http://www.czedma.cz)

## **Preamble**

This publication should contribute to understanding IVD area being an integral part of the Czech healthcare system. Even though IVD stand for only 2% of total healthcare costs, they are very important for the efforts of medical care personalization, and in the future they will play an important role in improving the quality of medical care in combination with a more efficient use of available resources.

The pressure on the Czech healthcare system is growing for two main reasons. Firstly, there is a great pressure for cutting down the costs in order to find a balance with insufficient resources, secondly, the demands for healthcare and use of new and progressive diagnostic and treatment methods are greater. Both of these aspects are going to become more and more serious with the ageing of the population.

The IVD industry has much to contribute to finding this balance. It is ready to supply technological and organizational solutions for optimization of a number of activities related to the production and use of diagnostic data that are integral parts of the healthcare system and a stepping stone for providing good quality healthcare services. Global statistics show that IVD is from 80% decisive for questions of further treatment, despite of IVD costs ranging only 2% of total healthcare costs in the Czech Republic.

This document presents information about the IVD market in the Czech Republic and its comparison with the EU market. It includes qualitative and quantitative indexes based on the last year data and showing prospective developments in near future. Our goal is to improve general awareness of this area which frequently lacks statistical data and therefore it is very complicated to quantify or assess its contributions to the overall healthcare system.

## **What is IVD?**

IVD is an abbreviation for “in vitro diagnostic” – Latin words with literal meaning of “diagnostics in glass”. It means that diagnosing, i.e. identification of a disease) is done outside of living organisms, through analyses of body fluids or tissue samples in a test tube, reaction cup, culture medium tray or glass board.

An example that everyone knows would be the taking of blood sample into a test tube that is then sent to a laboratory together with a dispatch note where the required tests are marked by the doctor.

In vitro diagnostic is the basic principle of many laboratory fields. The chief idea behind it is the measuring of content of some kind of substance in blood (or urine or other body liquids), measuring of physical properties of samples, microscopic cell testing, growing of microbiological cultures and the like.

IVD is used in laboratories of bacteriology, biochemistry, cytology, hematology, histology, immunology, microbiology, molecular biology, mycology, serology, virology... and a number of others.

Using in vitro diagnostic is very important for distinguishing the disease, frequently at a time when a patient notices no symptoms and no other diagnosing methods are able to identify the problem. Laboratory methods make it possible to find a disease at a time when the damage is still reversible and treatment usually easier.

Diagnosing and treating some diseases would be very difficult, if not impossible, without IVD, for instance:

- some infectious diseases, including hepatitis, HIV, but also measles or borrelia;
- diabetes and other metabolic disorders;
- kidney diseases;
- liver diseases;
- problems with the endocrinal system;
- but also ordinary pre-operative blood sedimentation test.

What is known as “screening” methods are methods of in vitro diagnostic used as a measure of prevention in large population samples when there is a suspicion of occurrence of a disease or spreading of an infection. IVD mean a great help here for early prevention measures. Also patients already suffering from a disease and on treatment or if a surgical operation is needed immediately – in all these cases not only clinical but also laboratory monitoring is required. It is exactly with the most serious diseases where changes in blood show whether treatment is successful or needs to be adjusted.

Thus, doctors have a way of verifying or specifying a diagnosis using objective laboratory findings. It is very important for them to make a full use of this instrument, especially in the area of primary care. It is always better to do a more expensive but targeted examination early in order to identify, confirm or rule out a diagnosis and to start with treatment as soon as possible. If a disease is distinguished early, sometimes mere dieting or preventive measures are sufficient. The best example is the testing of cholesterol level to establish the level of risk of cardiovascular diseases. Actual occurrence of this disease can then be prevented by going on a diet and changing one's lifestyle. ON the other hand, a belated diagnosis requires much more dramatic treatment together with other consequences for the patient's wellbeing and usually also with much higher financial costs.

## **The Czech healthcare system today and the important of IVD testing**

The Czech public healthcare insurance system was designed in order to make healthcare available to all, to separate the healthcare system financing from the state budget, to provide the citizens and healthcare providers with a choice, and to improve the quality of healthcare services provided. Most of these goals were achieved only thanks to major

investments made into the healthcare sector by the mid 1990s, however, the efficiency of using these investments was very often disputable, and a recent financial crisis showed that further extensive development of the sector is unsustainable. The measures taken to remedy the situation were limited to administrative regulation of costs and one-off financial subsidies without any systemic changes – the resulting problems clearly materialized when regional hospitals were transformed from state- to region-run organizations, and regularly make the news when the issue of clearing off debts of some hospitals is being discussed. A conceptual reform of the Czech healthcare system is being postponed because of disagreement among competent authorities. Only in 2004 there were three different ministers of healthcare appointed, each having a completely different vision of the future.

Today's reports on the state of health of the Czech population are not very good compared with other EU countries. The Czechs are high above average among the fifteen EU Member States in two categories: the occurrence rate of diabetes and high blood pressure. On the other hand, they benefit from outstanding preventive care in the area of examination of blood pressure and cholesterol level. The Czech Republic holds another not very flattering primacy – the length of hospitalization at ward blocks. The EU average is 1.3 nights per capita, while in the Czech Republic it ranges 2.7 nights, the reason usually being problems with circulatory system and cancer. Furthermore, the Czech Republic has one of the highest death and incidence rates for cancer. (*Source: ÚZIS ČR*)

**In this area, an effective use of IVD testing can make significant contributions to improving the diagnosing of serious diseases and monitoring of the success rate of treatment.** Thanks to scientific development and progress, the range of suitable methods of examination is growing, together with the use of advanced technologies that bring more accurate findings, and barrier-free communication and information-sharing among experts via the Internet. Organizations using IVD testing include hospitals as well private laboratories. Clear tendencies of consolidation and automation can be identified in both sectors, resulting in an increased labor efficiency but also shorter between taking a sample and delivering test results to patients (in urgent cases this can take only a few minutes). The Czech Republic's accession to the EU initiated the process of merging private laboratories into international groups.

#### **The Czech IVD legislation after May 1, 2004**

Pursuant to Act 22/1997 Coll. the in vitro diagnostic medical devices are classified as "defined" products which means that certain technical, marketing, operating and post-sale monitoring requirements are stipulated in applicable laws. These requirements are effective in the entire European Union and are defined in Directive 98/79/EC that was incorporated into national legislations of all the EU Member States. In the Czech Republic, the Directive was incorporate under Government Decree 453/2004 Coll. as of July 7, 2004, whereby it is now possible to market here only such IVD devices that are in full conformity with the Directive and the Government Decree no. 453, and bear the CE marking. The CE mark is a kind of verification for the user that the producer met all the legal requirements and that the product may be used in providing healthcare services as per Act 123/2000 Coll. as amended by Act 130/2003 Coll.

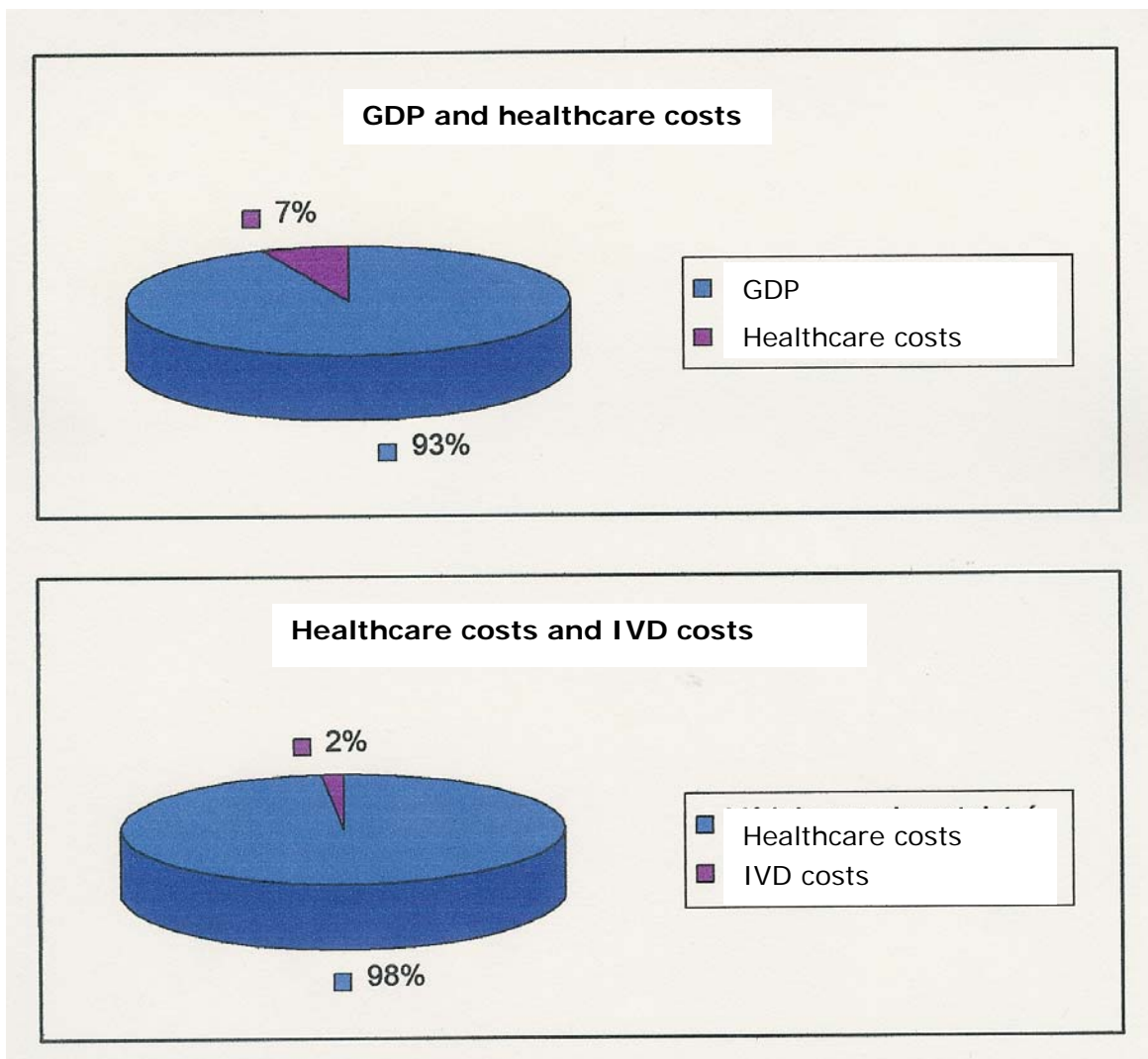
What are the fundamental provisions of Directive 98/79/EC (Government Decree 453/2004 Coll.)?

- Firstly, it defines what in vitro diagnostic medical devices are and what they are not.
- It stipulates the manner manufacturers are required to prove conformity of products with the legislative requirements.
- It stipulates the documentation manufacturers are required to submit, what records to keep and to what authorities and when these should be submitted.
- It defines basic requirements for IVD characteristics and performance.

- It stipulates in a great detail the information manufacturers are required to supply to users in manuals and on labels.
- It defined the scope of manufacturers' liability for IVD performance, provided all instructions and conditions of use given in manuals and on labels are complied with.
- It stipulates the obligation of all EU Member States to allow such products to enter their markets without any other requirements, limitations or restrictions.
- It grants each EU Member State the right to require that information supplied to users are in local languages.
- It grants each EU Member State the right to require additional information about specific IVD devices.

### IVD marketing under the economic conditions of the Czech healthcare sector

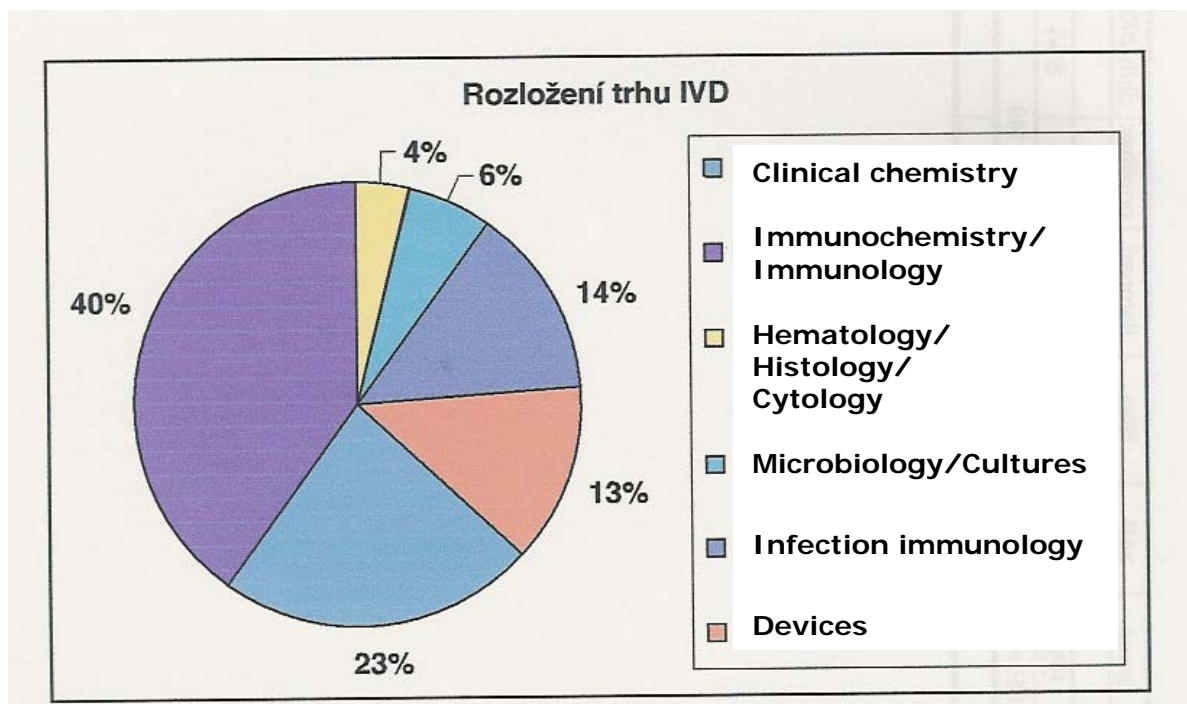
An estimated volume of costs accrued by healthcare institutions in relation to IVD testing equals approx. 1.8% of total healthcare costs, amounting to about CZK 3.3 billion.



IVD testing is performed by several hundred (400-600) laboratories operating in the Czech Republic – from small private laboratories with 2 technicians to large laboratories as the consolidate laboratories of large hospitals or major private laboratories serving general physicians and specialists in densely populated regions. The range and number of tests are adequate to the overall situation and highly varied with annual IVD costs ranging CZK 200,000 to CZK 100 million.

The VAT harmonization and reduction to 5% (as of May 1, 2004) meant great savings in IVD costs.

As regards the classification of costs, the most is invested into special hormonal testing, cardio and tumor markers, followed by diabetes and ordinary hematological testing, and biochemical and microbiological testing.



Due to the current setting of the healthcare system, patients are repeatedly tested for the same parameter and undergo redundant examinations unrelated to their actual disease.

**It is in the hands of competent authorities to introduce an efficient system where needless repetition of examination and testing can be avoided while supporting the use of IVD medical devices for early diagnosing and monitoring of successful treatment. This is the way major savings can be achieved in the healthcare sector. It is also a way of preventing further deterioration of patients' state of health and accruing more costs of treatment.**

There are several dozens suppliers of IVD devices in the Czech Republic with different volumes of sales and ranges. It is estimated that the 6 leading suppliers, most of them CZEDMA members, market over 90% of IVD devices (in terms of financial indexes).

Most IVD devices are imported from other countries, but there are some local producers who make deliveries directly to IVD users and usually export their products or supply some of the wholesalers. In the Czech Republic, all leading global IVD manufacturers are present.

Some suppliers cooperate with sub-distributors or specialized transport and logistic companies. IVD devices are supplied in the "just-in-time" regime, i.e. as fast as possible and directly from manufacturers to end users with maximum reduction of warehousing and loss of time. Most leading suppliers in the Czech Republic are holders of ISO 9000:2001 certificates.

Insurance companies have different coverage systems for IVD testing – from the rare per-performance system through lump sum payments to inclusion of basic testing in a treatment day at ward blocks. Each coverage system is different, subject to contractual agreements between insurance companies and healthcare service providers. Very few organizations actually cover the costs of IVD testing directly and from their own resources.

A majority of IVD devices are supplied in the form of diagnostic systems (devices + accessories + all necessary reagents + servicing), including long-term financing.

There are not many one-off investment projects for acquiring IVD technologies that usually take place when new healthcare institutions are developed. Suppliers for such projects are usually appointed in tender proceedings.

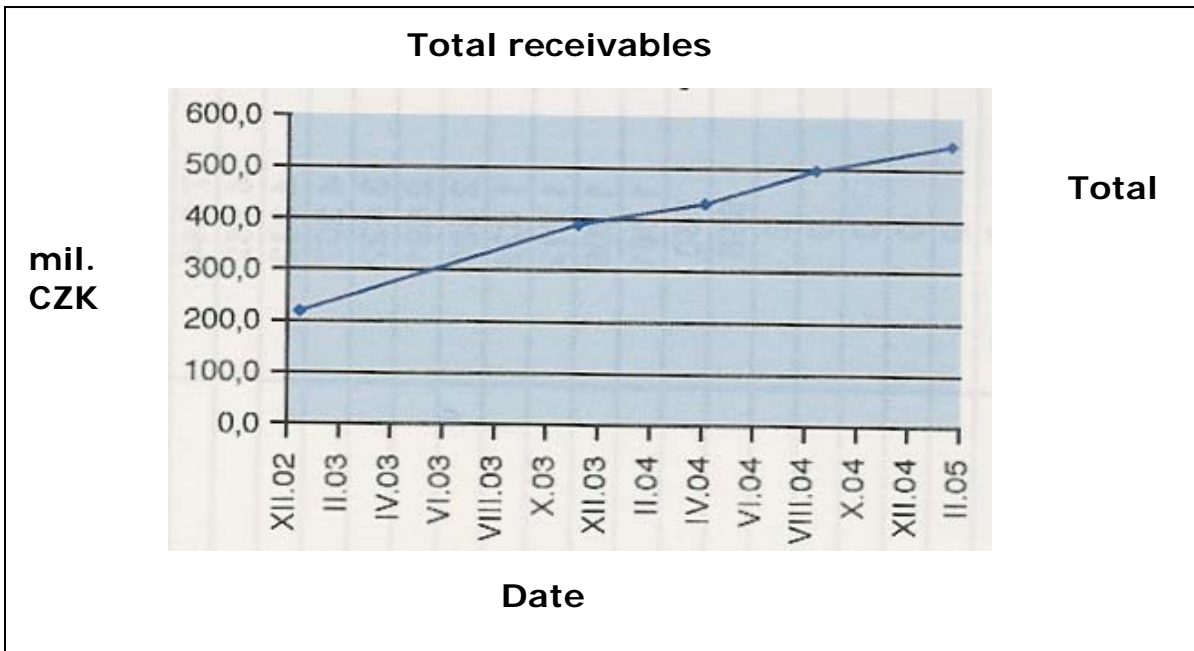
Most hospitals have the legal status of allowance organizations, which complicates the business cooperation with IVD devices suppliers. In this respect, the proposal of transforming these organizations into business partnerships seems to be a step in the right direction.

**Payments for IVD devices are supplies are unfortunately made only after the costs of wages, food, energy and pharmaceuticals are covered, thus generating very high and long-term receivables on the part of suppliers. Even large healthcare institutions take as long as 1 full year to pay for IVD devices supplies! On average, invoices are paid within 5 months after supply!**

The average volume of receivables 90 days past due date of IVD devices suppliers who are the CZEDMA members in the period between 2002 and August 2004 is summarized in the table below. It is clear that the volume rose to approx. CZK 0.53 billion, with total receivables nearly doubled (approx. CZK 1.12 billion).

**Total receivables of CZEDMA members from healthcare institutions in the period 2002-2005.**

Outstanding receivables (in mil. CZK)				
(days past due date)				
As of:	90 – 180 days	180-365 days	>365 days	Total
Dec. 31, 2002	105.5	86.7	28.1	<b>220.3</b>
Nov. 14, 2003	165.7	153.3	67.1	<b>386.1</b>
Mar. 31, 2004	219.4	162.0	49.3	<b>430.7</b>
Aug. 31, 2004	261.8	176.7	66.2	<b>504.7</b>
Mar. 31, 2005	253.9	185.4	94.9	<b>534.2</b>



**As of March 31, 2005, total receivables of CZEDMA members from healthcare institutions amounted to CZK 1.12 billion.**

IVD devices suppliers are forced to cover this high volume of outstanding receivables by loans from their parents companies or subcontractors, bank credits, factoring, etc. Other costs are accrued in relation to managing these debts. Due to this, supplying IVD devices is very complicated in terms of finances and existing risks. Even though the rate of recoverability of debts is quite high in this area, it can change the closing-down of unprofitable healthcare institutions starts.

#### **Conclusion**

**Modern medical services cannot do without IVD devices because no prevention or effective treatment is possible without them. IVD testing greatly contributes to improving healthcare services provided to patients. IVD devices are one of the key instruments of medical care personalization and adaptation to individual patient's needs.**

**IVD undergoes fast development and have great prospects. However, for this development to progress it is necessary that insurance companies introduce better systems of IVD devices acceptance for them to be used in practice as soon as possible. Finances used in relation to IVD are not costs but true investments in health.**

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