ISO 13485
ISO 15189
ISO 17043

todylaboratories®
Responsible diagnostic. Since 1993.

We produce and sell

- **services** accredited with ISO 15189 and ISO 17043
- **IVD products** accredited with ISO 13485

• **The free movement of products and services in the EU** is guaranteed by the Treaty establishing the European Community and the Treaty on European Union, amended by the Treaty of Lisbon in December 2007.
• **We manufacture services** based on our **ISO 15189:2013** credential, as we are meeting the requirements of this Standard, thus competent to perform activities of medical analysis and ensure the delivery of timely, accurate and reliable results. According to the EC Regulation no. 765/2008, „The particular value of accreditation lies in the fact that it provides an authoritative statement of the technical competence of bodies whose task is to ensure conformity with the applicable requirements". We are also ISO **17043:2010** accredited, fulfilling the requirements of this Standard, therefore competent to perform activities of providing proficiency testing schemes and of development and operation of proficiency testing schemes , both of these certificates being issued by a recognized EU Accreditation Body. These standards are published by the International Organization for Standardization (ISO) and refer on one hand to the quality management systems in the field of medical devices, including In Vitro Diagnostic. Although **ISO 13485** certification is voluntary, obtaining this certification allows us to meet the quality system requirements of the European Medical Device Directive (93/42/EEC) and In Vitro Diagnostic Medical Device Directive (98/79/EC) with less difficulty.
• **As manufacturer**, we have the responsibility not only to implement these quality management systems, but also to continuously operate them in such a way that regulatory needs are respected.