

-19%

**VAT
exempted
in the EU**

todylaboratories®

Responsible diagnostic. Since 1993.



Cut by 19% your actual cost with VAT rate

This cost advantage is valid for the **following ranges**:

1. **External Quality Assessment - EQA schemes**
2. **Internal Controls**, including:
3. **Reference Strains**, internal controls for microbiology
4. **Erythrocytes**, internal controls for transfusion

This **NO VAT cost advantage** is available for any laboratory in Europe who buys directly these ranges as laboratory services from other laboratory, as **todylaboratories®** is, **that has ISO 15189 and ISO 17043 accreditations**, not existing the legal obligation to collect VAT and Intrastat reporting, as in the case of purchasing these ranges as IVD products with CE mark, supplied by other companies that are not laboratories.

All these services are invoiced without VAT or reverse charge: **1.** because the above ranges **are not classified as IVDs**, according to their detailed definition from the EU Regulation no. 2017/746 on In Vitro Diagnostic medical devices: **a)** Section 1, Article 1 – Scope, definitions – “3. This Regulation does not apply to: (d) materials used for external quality assessment schemes.”; **b)** Article 2 – Definitions – 2nd alignment: “(2) ‘in vitro diagnostic medical device’ means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens...”. Therefore, all control samples are not IVD medical devices, as they are designed for “specimen testing”, they being specimens themselves (blood, serum, plasma etc.) for the examination of reagents, where the majority of them are derived from human organs (that cannot be subject of commerce and VAT application), as they are not IVD medical devices; **c)** Article 2 – Definitions – 5th alignment: “(5) ‘control material’ means a substance, material or article intended by its manufacturer to be used to verify the performance characteristics of a device.”; **d)** MEDDEV 2.14/1 revision 2 of January 2012 – Guidelines on medical devices, IVD Medical Device Borderline and Classification issues – document published by the European Commission, Directorate General for health and consumers, article 1.7. **Control Materials that are not IVD: Reference materials of higher order (Metrological traceability required) and Specific EQAS materials used for an external quality assurance system (Reference recital (9) of 98/97/EC).** **2.** because the above ranges fall under the 8690 CPV/NACE class of codes. Services provided by medical laboratories”, thus they do not fall under the 3360 CPV/NACE class of codes „pharmaceutical products”, as they are not IVD products for pharmaceutical use. **3.** because the above ranges have as object of supply the testing reports of the supplied samples, so no reagents with reaction substances are being delivered. **4.** because the above ranges are not part of the ranges that are subject to Intrastat reporting, in order to collect VAT, in conformity with EC Regulation no. 638/2004 of the European Parliament and of the Council of 31 March 2004 on Community statistics relating to the trading of goods between Member states - implemented by the Commission Regulation no. 638/2004 of the European Parliament and of the Council - article 1, where only the trading of goods is the subjected matter of this EC Regulation, which is establishing a common framework for the systematic production of Community statistics. **5.** because they are VAT exempt, according to the 2006/112/EC Directive on the common system of value added tax, where article 132 letter b) confirms that hospital and medical care and closely related activities undertaken by bodies governed by public law or, under social conditions comparable with those applicable to bodies governed by public law, by hospitals, centers for medical treatment or diagnosis and other duly recognized establishments of a similar nature are VAT exempt transactions.

We deliver **best practice** at economic costs. For medical laboratories.

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