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2017

External Control

- certified ISO 17043 and ISO 9001



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todylaboratories®

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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 **from 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 98/79/EC Directive on In Vitro Diagnostic medical devices: a) Recital (9): "Whereas, although internationally certified reference materials and materials used for external quality assessment schemes are not covered by this Directive, calibrators and control materials needed by the user to establish or verify performances of devices are in vitro diagnostic medical devices"; b) Article 1, letter (b): "in vitro diagnostic medical device" 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, 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 1, point (b): "3. For the purposes of this Directive, calibration and control materials refer to any substance, material or article intended by their manufacturer either to establish measurement relationships or to verify the performance characteristics of a device in conjunction with the intended use of that device; d) Article 21, point 2, letter (a): "Directive 93/42/EEC is hereby amended as follows: (a) in article 1(2); - point (c) shall be replaced by the following: "(c) „in vitro diagnostic medical device" 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, intended by the manufacturer to be used in vitro for the examination of specimens...". e) MEDDEV 2.14/1 revision 2 of January 2012 - Guidelines on medical devices, IVD Medical Device Borderline and Classification/issue - 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 98/79/EC". 2. because the above ranges they fall under the B20 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 subject 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.

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EQA Schemes



External Quality Assessment Schemes (EQAS)

Invaluable tools used by clinical laboratories to assess their analytical performance and achieve confidence in reporting their patients' test results

About **todylaboratories®**:

- We are authorized **EQA Schemes administrator** for clinical laboratories, since 2011, following the EU authorities procedure for ISO 9001 certification and fulfill the requirement of ISO GUIDE 43-1:1997
- We hold **ISO 17043 accreditation**, since 2016, fulfilling the requirements of this ISO, therefore competent to perform activities of development and operation for proficiency testing schemes
- We sell in EU **without VAT cost** all offered EQA Schemes as services ranges, as medical tests, that are not classified as IVDs, according to their detailed definition from the 98/79/EC Directive on In Vitro Diagnostic medical devices, Article 1, letter (b) and 9th paragraph

About the **EQA Schemes produced** by todylaboratories®:

- Comprised of many analytes, enrolled in different programmes, covering various clinical laboratory fields as well as the needs of small to large laboratories (clinical chemistry, hematology, immunology, urine chemistry, parasitology, microbiology etc)
- Provide **samples with a matrix similar to that of the patient samples** routinely tested in the clinical laboratory. The samples have various concentrations, spanning the entire clinical range, so that the participant laboratory can assess its method performance at all important decision levels
- Are accompanied by **clear and detailed instructions** for preparation and processing the samples. The results are submitted using specific, user-friendly result forms that can be sent by e-mail
- Submit **evaluation reports in simple assessment format**, shortly after receiving the results. Thus, each laboratory will be able to take corrective measures if problems are identified
- Are sustained by prompt professional support throughout the operation of each scheme
- Are operated with a **suitable frequency** that enables each laboratory to closely monitor its performance in terms of precision and accuracy
- Are characterized by **flexibility**: desired frequency, desired number of samples/round, registration up to different instruments at no extra cost, desired analytes to be reported in a program
- Have a considerable number of participating laboratories, that steadily increases every year

-19% VAT exempted in the EU

90 DAYS payment period

-10% BONUS applied value payment

FREE shipment

FREE samples

ISO 13485
ISO 15189
ISO 17043

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EQA SCHEMES

			2017				STANDARD PRICE EUR / report	SPECIAL PRICE -10% EUR / report	STANDARD PRICE USD / report	SPECIAL PRICE -10% USD / report				
EQA SCHEMES	PATHOLOGY	TQBP0050	Gynaecological cythology, Babes-Papanicolaou smear, 2 virtual images, 1 evaluation report, todylaboratories®				3	5	9	11	€ 37,41	€ 33,67	\$40,08	\$36,07
	BIOCHEMISTRY	TQBC0020	Clinical Chemistry, 1 sample, 1 evaluation report, todylaboratories®, 40 analytes: ALT, Uric acid, ALP, Amylase, AST, Total bilirubin, Direct bilirubin, Ionized calcium, Total calcium, Cholesterol, Cholesterol HDL, Cholesterol LDL, Creatinine, Iron, Gamma GT, Glucose, Chloride, Sodium, Potassium, Phosphorus, LDH, Magnesium, Protein, Triglycerides, Urea, Zinc, Albumin, Pancreatic amylase, Lithium, TIBC, Transferrin, Total CK, CK-MB, Lipase, Copper, CO2, IgA, IgE, IgG, IgM				3	5	9	11	€ 15,58	€ 14,03	\$16,70	\$15,03
		TQBC0020-2	Clinical Chemistry, 2 levels, 1 evaluation report, todylaboratories®, 40 analytes: ALT, Uric acid, ALP, Amylase, AST, Total bilirubin, Direct bilirubin, Ionized calcium, Total calcium, Cholesterol, Cholesterol HDL, Cholesterol LDL, Creatinine, Iron, Gamma GT, Glucose, Chloride, Sodium, Potassium, Phosphorus, LDH, Magnesium, Protein, Triglycerides, Urea, Zinc, Albumin, Pancreatic amylase, Lithium, TIBC, Transferrin, Total CK, CK-MB, Lipase, Copper, CO2, IgA, IgE, IgG, IgM				3	5	9	11	€ 26,54	€ 23,89	\$28,44	\$25,59
		TQEF0031	Protein electrophoresis, 1 sample, 1 evaluation report, todylaboratories®, 8 analytes: Total proteins, albumin, alfa 1 globulin, alfa 2 globulin, beta 1 globulin, beta 2 globulin, total beta globulins, gammaglobulins				3	5	9	11	€ 18,70	€ 16,83	\$20,04	\$18,03
	URINE CHEMISTRY	TQUR0022	Urine chemistry, strip test and identification of cells and other particles, 2 samples, 1 evaluation report, todylaboratories®, Strip test - 12 analytes: Blood, Glucose, hCG, Ketones, Leukocytes, Nitrite, pH, Protein, Relative density, Albumin, Bilirubin, Urobilinogen. Identification of cells and other particles - leukocytes, erythrocytes, casts, crystals and other particles				3	5	9	11	€ 14,34	€ 12,90	\$15,36	\$13,82
		TQUR0022-2	Urine chemistry, strip test and identification of cells and other particles, 2 levels, 1 evaluation report, todylaboratories®, Strip test - 12 analytes: Blood, Glucose, hCG, Ketones, Leukocytes, Nitrite, pH, Protein, Relative density, Albumin, Bilirubin, Urobilinogen. Identification of cells and other particles - leukocytes, erythrocytes, casts, crystals and other particles				3	5	9	11	€ 26,23	€ 23,61	\$28,11	\$25,30
		TQUQ0043	Urine, quantitative chemistry, 1 sample, 1 evaluation report, todylaboratories®, 14 analytes: Protein, Glucose, Microalbumin, Creatinine, Uric Acid, Calcium, Chloride, Cortisol, Magnesium, Osmolality, Phosphorus, Potassium, Sodium, Urea				3	5	9	11	€ 24,32	€ 21,88	\$26,05	\$23,45
	COAGULATION	TQCC0023	Coagulation, 1 sample, 1 evaluation report, todylaboratories®, 5 analytes: Prothrombin Time (Quick's time and INR), APTT, Fibrinogen, D-Dimer				3	5	9	11	€ 14,96	€ 13,47	\$16,03	\$14,43
	HEMATOLOGY	TQHG0026	HbA1c, 1 sample, 1 evaluation report, todylaboratories®, 1 analyte: glycated haemoglobin				3	5	9	11	€ 40,53	€ 36,47	\$43,42	\$39,08
		TQHM0021	Basic blood count, 1 sample, 1 evaluation report, todylaboratories®, 19 analytes: Hb, HCT, RBC, WBC, PLT, MCV, MCH, MCHC, MPV, RDW-SD, RDW-CV, LYM, MON, PCT, PDW, GRAN, EOZ, BAZ, NEU				3	5	9	11	€ 19,33	€ 17,39	\$20,71	\$18,63
		TQHM0021-2	Basic blood count, 2 levels, 1 evaluation report, todylaboratories®, 19 analytes: Hb, HCT, RBC, WBC, PLT, MCV, MCH, MCHC, MPV, RDW-SD, RDW-CV, LYM, MON, PCT, PDW, GRAN, EOZ, BAZ, NEU				3	5	9	11	€ 40,74	€ 36,66	\$43,65	\$39,28
		TQFL0036	Evaluation of blood cell morphology, 1 sample, 1 evaluation report, todylaboratories®, 2 analytes: Leucocyte differential count (manual method), evaluation of blood cell morphology				3	5	9	11	€ 26,81	€ 24,13	\$28,72	\$25,85
		TQFB0044	Faecal occult blood, 1 sample, 1 evaluation report, todylaboratories®, 1 analyte: Haemoglobin				3	5	9	11	€ 26,81	€ 24,13	\$28,72	\$25,85
		TQRT0047	Reticulocyte count, manual and automated method, 1 sample, 1 evaluation report, todylaboratories®, 1 analyte: reticulocyte count, manual and automated method				3	5	9	11	€ 27,12	€ 24,41	\$29,06	\$26,15
	HEPA TITIS	TQHP0027	Hepatitis A, B and C, 3 samples, 1 evaluation report, todylaboratories®, 4 analytes: HAVAb (anti-HAV), HAVAb IgM, HBsAg, HCVAb				3	5	9	11	€ 59,86	€ 53,87	\$64,13	\$57,72
	HIV	TQHV0028	HIV, antibodies, 1 sample, 1 evaluation report, todylaboratories®, 1 analyte: HIV Ab				3	5	9	11	€ 20,26	€ 18,23	\$21,71	\$19,54
	HORMONES AND TUMOR MARKERS	TQIM0024	Hormones and Tumor markers, quantitative and qualitative results, 2 samples (serum/urine), 1 evaluation report, todylaboratories®, 31 analytes: quantitative results from serum - T3, T4, Free T3, Free T4, TSH, LH, FSH, Estradiol, Progesterone, Testosterone, Prolactin, hCG, CEA, AFP, PSA, Free PSA, CA 125, CA 19-9, CA 15-3, CK, HGH, IgE, C-peptide, Insulin, Ferritin, 17-OH progesterone, Cortisol, Free-Estriol, DHEA-S, PTH, TPO Ab; qualitative results from serum - TSH, CEA, AFP, PSA, IgE; qualitative results from urine - LH, FSH				3	5	9	11	€ 27,43	€ 24,69	\$29,39	\$26,45



EQA SCHEMES

			2017				STANDARD PRICE EUR / report	SPECIAL PRICE -10% EUR / report	STANDARD PRICE USD / report	SPECIAL PRICE -10% USD / report
MICROBIOLOGY	TQBG0037-1	General bacteriology, 1 sample from any type of samples: cervical swab, urethral swab, ear swab, nasal swab, conjunctival swab, throat swab, faecal culture, urine culture etc, 1 evaluation report, todylaboratories®, 3 analytes: isolation of pathogens, culture and antimicrobial susceptibility testing	4	6	8	12	€ 34,25	€ 30,83	\$36,70	\$33,03
	TQCP0038	Faecal culture, 1 sample, 1 evaluation report, todylaboratories®, 3 analytes: isolation of pathogens, culture and antimicrobial susceptibility testing	4	6	8	12	€ 34,60	€ 31,14	\$37,07	\$33,36
	TQEX0040	Throat streptococcal culture, 1 sample, 1 evaluation report, todylaboratories®, 3 analytes: isolation of pathogens, culture and antimicrobial susceptibility testing	4	6	8	12	€ 34,60	€ 31,14	\$37,07	\$33,36
	TQFG0042	Gram stain, 1 sample, 1 evaluation report, todylaboratories®, 2 analytes: Gram stain and microscopy	4	6	8	12	€ 34,60	€ 31,14	\$37,07	\$33,36
	TQFN0048	Fungal culture, Candida, 1 sample, 1 evaluation report, todylaboratories®, 3 analytes: Candida - isolation, culture and antifungal susceptibility testing	4	6	8	12	€ 34,25	€ 30,83	\$36,70	\$33,03
	TQSB0411	Urethral swab, 1 sample, 1 evaluation report, todylaboratories®, 3 analytes: isolation of pathogens, culture and antimicrobial susceptibility testing	4	6	8	12	€ 36,47	€ 32,82	\$39,08	\$35,17
	TQSB0412	Cervical swab, 1 sample, 1 evaluation report, todylaboratories®, 3 analytes: isolation of pathogens, culture and antimicrobial susceptibility testing	4	6	8	12	€ 36,47	€ 32,82	\$39,08	\$35,17
	TQSB0413	Ear swab, 1 sample, 1 evaluation report, todylaboratories®, 3 analytes: isolation of pathogens, culture and antimicrobial susceptibility testing	4	6	8	12	€ 34,60	€ 31,14	\$37,07	\$33,36
	TQSB0414	Nasal swab, 1 sample, 1 evaluation report, todylaboratories®, 3 analytes: isolation of pathogens, culture and antimicrobial susceptibility testing	4	6	8	12	€ 34,60	€ 31,14	\$37,07	\$33,36
	TQSB0415	Conjunctival swab, 1 sample, 1 evaluation report, todylaboratories®, 3 analytes: isolation of pathogens, culture and antimicrobial susceptibility testing	4	6	8	12	€ 36,47	€ 32,82	\$39,08	\$35,17
	TQSB0416	Pus, 1 sample, 1 evaluation report, todylaboratories®, 3 analytes: isolation of pathogens, culture and antimicrobial susceptibility testing	4	6	8	12	€ 34,60	€ 31,14	\$37,07	\$33,36
	TQUC0039	Urine culture, 1 sample, 1 evaluation report, todylaboratories®, 3 analytes: isolation of pathogens, culture and antimicrobial susceptibility testing	4	6	8	12	€ 34,60	€ 31,14	\$37,07	\$33,36
	PARASITOLOGY	TQPS0046	Parasites in faeces, 1 sample, 1 evaluation report, todylaboratories®, 2 analytes: screening and identification of intestinal parasites	3	5	9	11	€ 26,81	€ 24,13	\$28,72
PREANALYTIC	TQFP0052	Preanalytical phase - case study from different domains - 3 study cases from chemistry, hematology, immunology or microbiology in which the participant should test the capacity to identify preanalytical errors and chose the appropriate behaviour to prevent their appearance. It is accepted from one participant to give several answers from different persons in laboratory	3	5	9	11	€ 15,43	€ 13,89	\$16,53	\$14,88
SEROLOGY	TQHE0035	Helicobacter pylori, Antibodies, 1 sample, 1 evaluation report, todylaboratories®, 1 analyte: anti-Helicobacter pylori antibodies	3	5	9	11	€ 19,64	€ 17,67	\$21,04	\$18,94
	TQHS0045	elicobacter pylori, Antigen detection in faeces, 1 sample, 1 evaluation report, todylaboratories®, 1 analyte: Helicobacter pylori antigen	3	5	9	11	€ 26,81	€ 24,13	\$28,72	\$25,85
	TQSR0030	Specific proteins, 1 sample, 1 evaluation report, todylaboratories®, 8 analytes: ASO, CRP, RF, C3, C4, IgA, IgG, IgM	3	5	9	11	€ 28,68	€ 25,81	\$30,73	\$27,66
	TQSS0034	Syphilis serology, 1 sample, 1 evaluation report, todylaboratories®, 3 analytes: RPR, VDRL, TPHA	3	5	9	11	€ 19,64	€ 17,67	\$21,04	\$18,94
TRANSFUSION / IMMUNOHEMATOLOGY	TQAB0033	ABO and Rh grouping, 1 sample, 1 evaluation report, todylaboratories®, 2 analytes: OAB and Rh grouping	3	5	9	11	€ 24,31	€ 21,88	\$26,05	\$23,44
	TQRH0051	Anti-Rh (Anti-D), Antibody screening and titration testing, 1 sample, 1 evaluation report, todylaboratories®, 2 analytes: antibody screening and titration testing	3	5	9	11	€ 25,92	€ 23,33	\$27,77	\$25,00
ESR	TQVS0032	ESR Erythrocyte sedimentation rate, 1 sample, 1 evaluation report, todylaboratories®, 1 analyte: ESR, manual and automated methods, no suitable for Alifax instruments	3	5	9	11	€ 33,36	€ 30,02	\$35,74	\$32,16

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 **Clinical Trials**

 **EQA Schemes**

 **Internal Control**

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 **Microbiology Reagents**

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 **Microbiology Stains**

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