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D I A G N O S T I C A G M B H

Quality Controls & Standard Materials

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in.vent Quality Controls

in.vent Quality Controls are designed to be used in Laboratory Quality Control Settings, in Quality Departments and R&D Units. They are applicable for solving tasks of precision, accuracy or correctness of in-vitro diagnostic assay measurements and analyte components throughout the whole value chain of in-vitro diagnostic test kits or assays.

in.vent Quality Controls are suitable for Internal Quality Control and also for External Quality Assurance such as Proficiency Testing and External Quality Assessment Schemes (EQAS) in Medical Laboratories. All Quality Controls consist of true native human materials or artificial matrices and are as identical to patient samples as possible. They are free of any additives unless the analytes or regulations require different production schemes.

All Quality Controls are tested with CE certified test systems and found negative or non-reactive for HIV I/II Ab, HBs Ag and HCV Ab.

in.vent Standard Quality Controls

Product Name	Analytes	Details	Pricing*
Cardiolipin Control	anti-Cardiolipin	Matrix: true human serum off the clot Levels: 1 Stability: 1 year at 2-8 °C Form: lyophilised	15.00 €/vial
Rheumatoid Arthritis Control	Rheumatoid Factor anti-CCP	Matrix: true human serum off the clot Levels: 2 Stability: 12 months at ≤ -15 °C; 2 months at 2-8 °C Form: liquid	23.00 €/vial
Thyroid Autoantibodies Control	anti-Tg anti-TPO TRAb	Matrix: true human serum off the clot Levels: 2 Stability: 5 years at 2-8 °C Form: lyophilised	25.00 €/vial
In.QualiCheck Prostate Specific Antigen Control QC 2.1.8	PSA, total PSA, free	Matrix: true human serum off the clot Levels: 2 Stability: 2 years at 2-8 °C Form: lyophilised	28.00 €/vial
In.QualiCheck Procalcitonin Control QC 2.1.16, QC 2.1.17, QC 2.1.18	PCT	Matrix: true human serum off the clot Levels: 3 Stability: 12 months at ≤ -15 °C; 2 months at 2-8 °C Form: lyophilised	20.00 €/vial
In.QualiCheck Calprotectin Control QC. 2.1.20, QC 2.1.21, QC 2.1.22	Calprotectin	Matrix: faeces Levels: 3 Stability: 12 months at 2-8 °C Form: lyophilised	30.00€/vial
Calprotectin-Elastase Control	Calprotectin Elastase	Matrix: faeces Levels: 2 Stability: 12 months at 2-8 °C Form: lyophilised	30.00 €/vial
SARS-CoV-2 IgG/IgM Serum Control	SARS-CoV-2 IgG (IgM values on availability)	Matrix: true human serum off the clot Levels: 2 Stability: 6 months at 2-8 °C Form: lyophilised	25.00 €/vial
CRP Control	CRP	Matrix: true human serum off the clot Levels: 8 Stability: 12 months at 2-8 °C Form: lyophilised	20.00 €/vial
Faecal Diagnostic – Faecal Occult Blood	Haemoglobin	Matrix: faeces Levels: 2 Stability: 12 months at 2-8 °C Form: lyophilised	20.00 €/vial

Data sheets for each product are available on request.

* Minimum purchase: 1 batch of 500 vials

in.vent Customized Quality Controls

in.vent Individual Quality Controls are produced according to detailed customer requirements. They are useable for internal Laboratory Performance Monitoring as well as for Proficiency Testing. Production of CE-labelled Controls available.

Examples of Analytes for your customised and individually developed Quality Control:

Indication	Analytes / Parameter*	Price Category
Allergy		
Inhalation	e.g. d01, d02, e01, g06, g12, t03, t04, w06, total IgE	A
Insecticides	e.g. i01, i03, total IgE	A
Food	e.g. f02, f03, f04, f05, f09, f13, f14, f17, f49, f84, total IgE	A
Autoimmunity		
Antiphospholipidsyndrome	anti-Cardiolipin, anti-beta 2 Glycoprotein I	B
Diabetes mellitus	anti-GADA, anti-ICA, anti-IAA, anti-IA2, HbA1c	A
Diabetes mellitus	HbA1c	C
Collagenosis	anti-ds DNA, anti-SSA/Ro (60kD), anti-SSB/La, anti-Scl 70, anti-U1-snRNP	B
Rheumatoid Arthritis	Rheumatoid Factor, anti-CCP	B
Thyroid Autoantibodies	anti-TPO, anti-Tg, anti-TSH receptor	B
Vasculitis/Glomerulonephritis	anti-GBM, anti-MPO, anti-PR3	B
Faecal Diagnostic		
Crohn`s Disease/Colitis ulcerosa	Calprotectin, Pancreatic Elastase, Lactoferrin	B
Faecal Occult Blood	Haemo-/ Haptoglobin, Free Haemoglobin	B
Gammopathies		
Gammopathies	IgA, IgG, IgM, Kappa-type free light chain, Lambda-type free light chain	C
Haemostasis		
Thrombosis	D-Dimer	B
Hormones		
Thyroid Gland	T3, T3 (free), T4, t4 (free). TSH	B
Fertility	AFP, AMH, free beta-chain hCG, hCG intact, free Estriol, FSH, LH, PAPP-A	A
Infectious Diseases		
Chlamydiae	anti-Chlamydia pneumoniae, anti-Chlamydia trachomatis	A
SARS-CoV-2	SARS-CoV-2 IgG (IgM values on availability)	B
Sepsis	Procalcitonin, CRP	A
Metabolism		
Kidney Metabolism	Hormones, Metabolites, Glucosid	A
Bone Metabolism	Vitamin D 25-hydroxy-cholecalciferol, Vitamin D, CTX, PTH, Osteocalcin, P1NP	C
Oncology		
Cancer/Tumor Marker	AFP, B _h CG, CA15-3, CA 19-9, CA 50, CA 72-4, CA 125, Calcitonin, CEA, CRP, Cyfra 21-1, hCT, FSH, LH, NSE, PSA free, PSA Total, TSH	C



Additional Information

Bottling	production of individual batches 100 - 5.000 samples
Form	liquid frozen or lyophilised
Source Material	native human materials disease state and/or spiked
CE-Controls	available on request

Price Categories

A	< 25.00 €/vial
B	25.00 - 30.00 €/vial
C	> 30.00 €/vial

in.vent Standard Materials

In addition to our standardised and individual quality controls, we provide you with material that you can use for your own production. Furthermore, we offer you controls and sample material with different parameters for every step in the value chain of in-vitro diagnostics.



Normal Donation Pools

in.vent Normal Human Serum and CPD Plasma Pools are designed for the use throughout the whole value chain of in-vitro diagnostic test kits, e.g. for R&D and Quality Control Departments. Human Serum and CPD Plasma is used for production purposes like production of standards, calibrators or controls for IVDs or EQAS. For non-therapeutic, in-vitro-diagnostic use only.

Pools of Normal Human Citrate-Phosphate-Dextrose Plasma (CPD Plasma)

Product Name	Volume	Content	Pricing
CPD Pool	1.0l	pool of CPD donations, not further specified	600.00 €
CPD Pool - Gender Mix	1.0l	pool of CPD donations, 50% female – 50% male donors	600.00 €
CPD Pool - Gender Female	1.0l	pool of CPD donations, 100% female donors	600.00 €
CPD Pool - Male	1.0l	pool of CPD donations, 100% male donors	600.00 €
CPD Pool - AB Male	1.0l	pool of CPD donations, 100% male donors	650.00 €
CPD Pool - Low Triglycerides	1.0l	pool of CPD donations, gender not specified, with low titers of triglycerides	650.00 €
CPD Pool – AB Mix	1.0l	pool of CPD donations, 50% female – 50% male donors	650.00 €

Data sheets for each product are available on request.

Additional Information

Matrix	Normal Human Citrate-Phosphate-Dextrose Plasma (CPD Plasma)
Filtration	the product is filtered: 0.2µm
Disease State Testing	tested by CE marked test systems and found negative for HIV I/II antibodies, HBsAg, HCV antibodies
Delivered Information on Certificate	product number, matrix, volume, minimum shelf life, result of laboratory testing (if applicable)

Pools of Normal Human Sera

Product Name	Volume	Content	Pricing
Normal Human Serum Pool	1.0l	Pool of donations, not further specified	2,600.00 €
Normal Human Serum Pool - AB Mix	1.0l	Pool of donations, male and female	2,650.00 €
Normal Human Serum Pool - Female	1.0l	Pool of donations 100% female	2,650.00 €
Normal Human Serum Pool - AB Male	1.0l	Pool of donations 100% male	2,700.00 €

Data sheets for each product are available on request.

Additional Information	
Matrix	true human serum off the clot ¹
Filtration	the pool is filtered: 0.2µm
Disease State Testing	tested by CE marked test systems and found negative for HIV I/II antibodies, HBsAg, HCV antibodies
Delivered Information on Certificate	product number, matrix, volume, minimum shelf life, result of infectious disease testing

¹ True human Serum off the clot (OTC) is collected from blood that is allowed to coagulate naturally after collection. It has not been exposed to any anticoagulant. Clotting is completed after 20 to 30 minutes. Afterwards the sample is centrifuged.

Disease State Pools

in.vent Disease State Pools are designed for the use throughout the whole value chain of in-vitro diagnostic test kits, e.g. for R&D and Quality Control Departments. They are used for production purposes like production of standards, calibrators or controls for IVDs or EQAS. For non-therapeutic, in-vitro-diagnostic use only.

Product Name	Volume	Pricing
Allergy - Specific IgE	1.0 l	7,000.00 €
Rheumatoid Arthritis	1.0 l	11,000.00 €
CDT 1.0 L	1.0 l	11,000.00 €
Toxoplasma gondii IgM	1.0 l	11,000.00 €
Toxoplasma gondii IgM high positive	1.0 l	14,000.00 €
PCT Serum 1.0 l (Bottling 100 ml)	1.0 l	8,000.00 €
CRP Serum 1.0 l (Bottling 100 ml)	1.0 l	8,000.00 €
anti-Tg Antibodies positive, sodium-citrate plasma	1.0 l	11,000.00 €
anti-TPO Antibodies positive, sodium-citrate plasma	1.0 l	11,000.00 €
anti-TSH receptor Antibodies (TRAb), plasma	1.0 l	11,000.00 €
Anti-TPO Serum - converted / defibrinated	1.0 l	12,000.00 €

Additional Information	
Matrix	true human serum off the clot ¹
Disease State Testing	tested by CE marked test systems and found negative for HIV I/II antibodies, HBsAg, HCV antibodies
Delivered Information on Certificate	product number, matrix, volume, minimum shelf life, result of infectious disease testing

Notes:

Contact & Ordering Information



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