# We are human





# **Quality Controls & Standard Materials**

Extract of our Portfolio 2022/23



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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 QC.P 5.2.1.1	anti-Cardiolipin	Matrix: true human serum off the clot Levels: 1 Stability: 1 year at 2-8 °C Form: lyophilisied	15.00 €/vial
Rheumatoid Arthritis Control QC.P 5.3.1.1	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
<b>Thyroid Autoantibodies Control</b> QC.P 15.2.1.1	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: 4 years at 2-8 °C Form: lyophilised	28.00 €/vial
<b>In.QualiCheck Procalcitonin Control</b> QC 2.1.16	РСТ	Matrix: true human serum off the clot Levels: 3 Stability: 12 months at ≤ -15 °C; 2 months at 2-8 °C Form: lyophilised	15.00 €/vial
Calprotectin-Elastase Control QC.P 16.3.5.1	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 QC 2.1.13	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
<b>CRP Control</b> QC 2.1.14	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 QC 2.2.10	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 Individual 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	cation Analytes / Parameter*			
Allergy		Price Category		
Inhalation	e.g. d01, d02, e01, g06, g12, t03, t04, w06, total IgE	А		
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	1			
Antiphospholipidsyndrome	anti-Cardiolipin, anti-beta 2 Glycoprotein I	В		
Diabetes mellitus	anti-GADA, anti-ICA, anti-IAA, anti-IA2, HbA1c	А		
Collagenosis	anti-ds DNA, anti-SSA/Ro (60kD), anti-SSB/La, anti-Scl 70, anti-U1-snRNP	В		
Rheumatoid Arthritis	Rheumatoid Factor, anti-CCP	В		
Thyroid Autoantibodies	anti-TPO, anti-Tg, anti-TSH receptor	В		
Vasculitis/Glomerulonephritis	anti-GBM, anti-MPO, anti-PR3	В		
Faecal Diagnostic	-			
Crohn`s Disease/Colitis ulcerosa	Calprotectin, Pancreatic Elastase, Lactoferrin	В		
Faecal Occult Blood	Haemo-/ Haptoglobin, Free Haemoglobin	В		
Gammopathies	-			
Gammopathies	IgA, IgG, IgM, Kappa-type free light chain, Lambda-type free light chain			
Haemostasis				
Thrombosis	Thrombosis D-Dimer			
Hormones				
Thyroid Gland	T3, T3 (free), T4, t4 (free). TSH	В		
Fertility	tility AFP, AMH, free beta-chain hCG, hCG intact, free Estriol, FSH, LH, PAPP-A			
Infectious Diseases				
Chlamydiae	anti-Chlamydia pneumoniae, anti-Chlamydia trachomatis	А		
SARS-CoV-2	2 SARS-CoV-2 IgG (IgM values on availability)			
Sepsis	epsis Procalcitonin, CRP			
Metabolism				
Kidney Metabolism	Metabolism Hormones, Metabolites, Glucosis			
Bone Metabolism	Vitamin D 25-hydroxy-cholecalciferol, Vitamin D, CTX, PTH, Osteocalcin, P1NP	С		
Oncology				
Cancer/Tumor Marker	AFP, BhCG, CA15-3, CA 19-9, CA 50, CA 72-4, CA 125, Cal- citonin, 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		
Α	< 25.00 €/vial	
В	25.00 - 30.00 €/vial	
С	> 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-vitrodiagnostic use only.

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

Product Number	Product Name	Volume	Content	Pricing
NDPO.P 4.2.1.1	CPD Pool	1.01	pool of CPD donations, not further specified	600.00€
NDPO.P 4.2.1.3	CPD Pool - Gender Mix	1.01	pool of CPD donations, 50% female – 50% male donors	600.00€
NDPO.P 4.2.1.5	CPD Pool - Gender Female	1.01	pool of CPD donations, 100% female do- nors	600.00€
NDPO.P 4.2.1.7	CPD Pool - Male	1.01	pool of CPD donations, 100% male donors	600.00€
NDPO.P 4.2.1.9	CPD Pool - AB Male	1.01	pool of CPD donations, 100% male donors	650.00€
NDPO.P 4.2.1.11	CPD Pool - Low Triglycerides	1.01	pool of CPD donations, gender not specified, with low titers of triglycerides	650.00 €
NDPO.P 4.2.1.13	CPD Pool – AB Mix	1.01	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-
Filtration	the product is filtered:
Disease State Testing	tested by CE marked te HBsAg, HCV antibodies
Delivered Information on Certificate	product number, matrix (if applicable)

-Phosphate-Dextrose Plasma (CPD Plasma)

0.2µm

test systems and found negative for HIV I/II antibodies,

ix, volume, minimum shelf life, result of laboratory testing

### **Pools of Normal Human Sera**

Product Number	Product Name	Volume	Content	Pricing
NDPO.P 4.2.3.1	Normal Human Serum Pool	1.01	Pool of donations, not further specified	2,600.00€
NDPO.P 4.2.3.3	Normal Human Serum Pool – AB Mix	1.01	Pool of donations, male and female	2,650.00€
NDPO.P 4.2.3.7	Normal Human Serum Pool – Female	1.01	Pool of donations 100% female	2,650.00€
NDPO.P 4.2.3.9	Normal Human Serum Pool – AB Male	1.01	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 <sup>1</sup>	
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	

<sup>1</sup> 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 Number	Product Name	Volume	Pricing
DSPO.P 4.2.10.2	Allergy Pool - Specific IgE	1.0	7,000.00€
DSPO.P 5.17.2.2	Rheumatoid Arthritis	1.0	11,000.00€
DSPO.P 9.2.10.2	CDT Pool 1.0 L	1.0	11,000.00€
DSPO.P 9.2.10.9	CDT Pool 100 ml	100.0 ml	2,500.00€
DSPO.P 12.51.6.2	Toxoplasma gondii IgM	1.0	11,000.00€
DSPO.P 12.51.6.92	Toxoplasma gondii IgM high positive	1.0	14,000.00€
DSPO.P 14.2.1.2	PCT Serum Pool 1.0 I (Bottling 100 ml)	1.0	8,000.00€
DSPO.P 14.3.1.2	CRP Serum Pool 1.0 I (Bottling 100 ml)	1.0	8,000.00€
DSPO.P 15.3.26.2	anti-Tg Antibodies positive, human plasma, sodium-citrate plasma	1.0	11,000.00€
DSPO.P 15.2.26.2	anti-TPO Antibodies positive, human plasma, sodium-citrate plasma	1.0	11,000.00€
DSPO.P 15.4.2.2	anti-TSH receptor Antibodies (TRAb), human plasma	1.0	11,000.00€
DSPO.P 15.2.1.2	Anti-TPO Serum - Pool (converted / defibrinated)	1.0	12,000.00€

Additional Information	
Matrix	true human serum off the clot or native human sodium-citrate plasma
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**





# General Contact +49 (0)3302 55 199 0 info@inventdiagnostica.de

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## **Contact for your Order** sales@inventdiagnostica.de

Please send us your individual requests via: inquiry.inventdiagnostica.de





# www.inventdiagnostica.de