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**in.vent**  
D I A G N O S T I C A G M B H

# Quality Controls & Standard Materials

Extract of our Portfolio  
2020/21



# 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*
<b>Cardiolipin Control</b> QC 2.1.1	anti-Cardiolipin	Matrix: true human serum off the clot Levels: 1 Stability: 1 year at 2-8 °C Form: lyophilised	15.00 €/vial
<b>Rheumatoid Arthritis Control</b> QC 2.1.2	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 2.1.4	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
<b>Prostate Specific Antigen Control</b> QC 2.1.10	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>Procalcitonin Control</b> QC 2.1.11	PCT	Matrix: true human serum off the clot Levels: 4 Stability: 12 months at ≤ -15 °C; 2 months at 2-8 °C Form: lyophilised	15.00 €/vial
<b>Calprotectin-Elastase Control</b> QC 2.1.12	Calprotectin Elastase	Matrix: faeces Levels: 2 Stability: 12 months at 2-8 °C Form: lyophilised	28.00 €/vial
<b>SARS-CoV-2 IgG/IgM Serum Control</b> 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
<b>Faecal Diagnostic – Faecal Occult Blood</b> 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	Analytes / Parameter*	Price Category
<b>Allergy</b>		
<b>Inhalation</b>	e.g. d01, d02, e01, g06, g12, t03, t04, w06, total IgE	A
<b>Insecticides</b>	e.g. i01, i03, total IgE	A
<b>Food</b>	e.g. f02, f03, f04, f05, f09, f13, f14, f17, f49, f84, total IgE	A
<b>Autoimmunity</b>		
<b>Antiphospholipidsyndrome</b>	anti-Cardiolipin, anti-beta 2 Glycoprotein I	B
<b>Diabetes mellitus</b>	anti-GADA, anti-ICA, anti-IAA, anti-IA2, HbA1c	A
<b>Collagenosis</b>	anti-ds DNA, anti-SSA/Ro (60kD), anti-SSB/La, anti-Scl 70, anti-U1-snRNP	B
<b>Rheumatoid Arthritis</b>	Rheumatoid Factor, anti-CCP	B
<b>Thyroid Autoantibodies</b>	anti-TPO, anti-Tg, anti-TSH receptor	B
<b>Vasculitis/Glomerulonephritis</b>	anti-GBM, anti-MPO, anti-PR3	B
<b>Faecal Diagnostic</b>		
<b>Crohn`s Disease/Colitis ulcerosa</b>	Calprotectin, Pancreatic Elastase, Lactoferrin	B
<b>Faecal Occult Blood</b>	Haemo-/ Haptoglobin, Free Haemoglobin	B
<b>Gammopathies</b>		
<b>Gammopathies</b>	IgA, IgG, IgM, Kappa-type free light chain, Lambda-type free light chain	C
<b>Haemostasis</b>		
<b>Thrombosis</b>	D-Dimer	B
<b>Hormones</b>		
<b>Thyroid Gland</b>	T3, T3 (free), T4, t4 (free). TSH	B
<b>Fertility</b>	AFP, AMH, free beta-chain hCG, hCG intact, free Estriol, FSH, LH, PAPP-A	A
<b>Infectious Diseases</b>		
<b>Chlamydiae</b>	anti-Chlamydia pneumoniae, anti-Chlamydia trachomatis	A
<b>SARS-CoV-2</b>	SARS-CoV-2 IgG (IgM values on availability)	B
<b>Sepsis</b>	Procalcitonin, CRP	A
<b>Metabolism</b>		
<b>Kidney Metabolism</b>	Hormones, Metabolites, Glucosis	A
<b>Bone Metabolism</b>	Vitamin D 25-hydroxy-cholecalciferol, Vitamin D, CTX, PTH, Osteocalcin, P1NP	C
<b>Oncology</b>		
<b>Cancer/Tumor Marker</b>	AFP, BhCG, 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	
<b>Bottling</b>	production of individual batches 100 - 5.000 samples
<b>Form</b>	liquid frozen or lyophilised
<b>Source Material</b>	native human materials disease state and/or spiked
<b>CE-Controls</b>	available on request

Price Categories	
<b>A</b>	< 20.00 €/vial
<b>B</b>	20.00 - 25.00 €/vial
<b>C</b>	> 25.00 €/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 Number	Product Name	Volume	Content	Pricing
NDPO 4.2.1.1	CPD Pool	1.0l	pool of CPD donations, not further specified	720.00 €
NDPO 4.2.1.3	CPD Pool - Gender Mix	1.0l	pool of CPD donations, 50% female – 50% male donors	720.00 €
NDPO 4.2.1.5	CPD Pool - Gender Female	1.0l	pool of CPD donations, 100% female donors	720.00 €
NDPO 4.2.1.7	CPD Pool - Male	1.0l	pool of CPD donations, 100% male donors	780.00 €
NDPO 4.2.1.9	CPD Pool - AB Male	1.0l	pool of CPD donations, 100% male donors	780.00 €
NDPO 4.2.1.11	CPD Pool - Low Triglycerides	1.0l	pool of CPD donations, gender not specified, with low titers of triglycerides	780.00 €
NDPO 4.2.1.13	CPD Pool – AB Mix	1.0l	pool of CPD donations, 50% female – 50% male donors	780.00 €
NDPO 4.2.1.CS	Customised CPD Plasma Pool		“Customised CPD Plasma Pool” is exclusively derived by customers projects. Please send specifications for an individualised offer.	

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 Number	Product Name	Volume	Content	Pricing
NDPO 4.2.3.1	Normal Human Serum Pool	1.0l	Pool of donations, not further specified	650.00 €
NDPO 4.2.3.3	Normal Human Serum Pool – AB Mix	1.0l	Pool of donations, male and female	950.00 €
NDPO 4.2.3.7	Normal Human Serum Pool – Female	1.0l	Pool of donations 100% female	950.00 €
NDPO 4.2.3.9	Normal Human Serum Pool – AB Male	1.0l	Pool of donations 100% male	950.00 €
NDPO 4.2.3.CS	Customised Serum Pool		“Customised Serum Pool” is exclusively derived by customers projects. Please send specifications for an individualised offer.	

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: 0.2 µm
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
ALPO 4.1.7.1.1	Allergy Pool - Specific IgE	1.0 l	8,000.00 €
DSPO 4.1.1.1.1	Rheumatoid Arthritis Pool	1.0 l	12,000.00 €
DSPO 4.1.9.1.1	SARS-CoV-2 Pool	1.0 l	5,000.00 €
DSPO 4.2.1.1.2	CDT Pool	100.0 ml	9,000.00 €
DSPO 4.1.7.1.1	Toxoplasma gondii IgM Pool	10.0 l	8,000.00 €
DSPO 4.1.5.1.1	Procalcitonin (PCT) Pool	1.0 l	7,000.00 €
DSPO 4.1.5.1.2	C-Reactive Protein (CRP) Pool	1.0 l	7,000.00 €
DSPO 4.1.6.4.3	anti-Thyroidperoxidase (TPO) Pool	5.0 l	7,000.00 €
DSPO 4.1.6.4.4	anti-Thyroglobulin (Tg) Pool	5.0 l	7,000.00 €
DSPO 4.1.6.4.5	anti-TSH receptor (TRAb) Pool	5.0 l	7,000.00 €

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

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## Contact for your Order

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**Please send us your individual requests via:**

**inquiry.inventdiagnostica.de**

