

# Product List

2017/18

Human Biomaterials

*We are human*



# Contact & Ordering Information



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**in.vent Diagnostica** is a biomedical company with its headquarter at the biotech campus in Hennigsdorf, near Berlin. We are active in the field of ethical correct procurement of human bio-materials since 1999.

**in.vent** is focussed on the customized procurement of human bio-materials. Further fields of activities are the production of biomarkers from human origin, quality controls, standard materials and diagnostic clinical studies.

**in.vent** is Europe's leading specialist for ethical correct procurement of high quality bio-materials. State-of-the-art production of biomolecules of human origin as well as challenging contract development of in-vitro-diagnostics (IVD) are further core competences of our team.

**in.vent**'s clients profit from the team of high qualified scientists with extensive and deep knowledge of human bio-materials and its thorough understanding of assay development.

**in.vent** fully complies with ethical correct behaviour and strictly follows ethical guidelines and values which are updated on a regular basis.

**in.vent** always strives to achieve highest satisfaction of customers.

**in.vent** is certified according to ISO 9001 and ISO 13485.

### We like to meet your challenges

## Ethical Principles and Values of in.vent

in.vent is committed to the highest international ethical and legal standards.

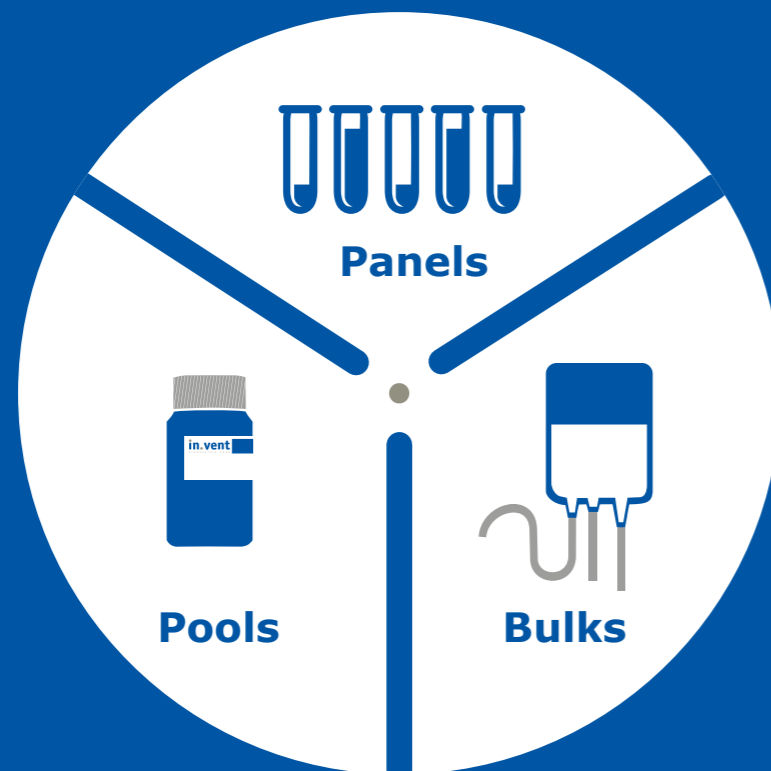
This statement underlines our firm commitment to ethical correct behaviour of all our doing.

1. The Declaration of Helsinki<sup>i</sup> as developed by the World Medical Association states the ethical principles that provide guidance to physicians and other participants in medical research involving human subjects is basis of our guidelines.
2. in.vent only cooperates with networks, physicians, clinics and other organizations that comply with these standards.
3. Further standards are based on the statements of the MPG<sup>ii</sup> (Medical Device Directive), which adopts the European Guideline 98/79/EG<sup>iii</sup> for in-vitro-Diagnostica into national law.
4. At regular intervals audits are carried out that give suggestions for process improvement apart from target alignment.
5. The notes of the German Central Ethical Committee<sup>iv</sup> and the German Ethicsboard regarding biobanks for research purposes are taken into consideration as well as far as they are applicable.
6. Furthermore ICH-GCP guidelines<sup>v</sup> (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use – Good Clinical Practise) are taken into account whenever applicable.

- human biomaterials are valuable biomaterials needed but not restricted to medical research, development and production of IVDs, companion diagnostics, pharmaceutical and diagnostical trials
- human biomaterials can be leftovers, tissues and body fluids from operations or from laboratory diagnostics as well as donations procured for medical or scientific reason
- all donations are preceded by statements according the ethical correctness of the projects of an International Review Board (IRB)<sup>vi</sup> resp. ethical boards and committees, whenever applicable
- the use of human biomaterials is part of the personal rights of each single donor, therefore we commit to obtain informed donor consents in writing whenever it is of relevance
- donors may have limited knowledge in medical and pharmaceutical topics, therefore all signing of informed donor consents is preceded by detailed explanations to the donor. These explanations include all purposes, ways and lengths of use and all detailed information regarding the use of the donated biomaterials
- all use of donated materials was, is and will be restricted to the purposes respectively the application the donor agreed to
- all personal data referring to donated biomaterials are pseudonymized resp. anonymized before being transferred to third parties
- The use of all personal data is restricted and confidential according all applicable laws and regulations and is closely monitored
- in.vent maintains a Quality Control System (ISO 9001)<sup>vii</sup> and is as well certified according to ISO 13485<sup>viii</sup>
- The compliance with the above mentioned guidelines is kept under strict surveillance
- in.vent trains and informs its employees to ensure compliance with these guidelines on a regularly basis

i [www.wma.net/en/30publications/10policies/b3/index.html](http://www.wma.net/en/30publications/10policies/b3/index.html)  
 ii [www.gesetze-im-internet.de/bundesrecht/mpg/gesamt.pdf](http://www.gesetze-im-internet.de/bundesrecht/mpg/gesamt.pdf)  
 iii [www.gesetze-im-internet.de/bundesrecht/mpg/gesamt.pdf](http://www.gesetze-im-internet.de/bundesrecht/mpg/gesamt.pdf)  
 iv [www.ce-richtlinien.eu/richtlinien/InVitDiag.html](http://www.ce-richtlinien.eu/richtlinien/InVitDiag.html)

v [www.ich.org/products/guidelines.html](http://www.ich.org/products/guidelines.html)  
 vi [www.feki.com/index.php?id=10](http://www.feki.com/index.php?id=10)  
 vii [www.iso9001.qmb.info/](http://www.iso9001.qmb.info/)  
 viii [www.praxion.com/iso-13485.htm](http://www.praxion.com/iso-13485.htm)



# Panels, Pools and Bulks by in.vent

- for academic research, studies, development and production
- off-the-shelf, prospective collections or tailored samples
- deeply characterized samples
- customized pre-analytics
- tailored testing for infectious diseases
- global collection capabilities and company-owned donation center
- just in time adapted delivery

Sample **sourcing** at in.vent always fulfills all requirements regarding ethics. Ethic approvals, informed donor consent e.g. are available as requested by the customer and tailored according to project requirements.

**Volumes** are available from 0.1 µl up to thousands of liters.

Standard **product presentation** is liquid frozen. Tailored product presentation may be lyophilized e.g.

Standard **information** are age, gender, indication resp. titer of analytes. Additional information are available on request adapted to customer's projects. Additional information may include BMI, smoking, therapies, anamnestic data, follow up data e.g.

Customized **preanalytics** are available on request too. Preanalytics may include specific blood sampling tubes, processing, storage, specific preparations of donors like fasting, consideration of circadian rhythm e.g.

Standard **storage** of samples is < -18 °C. Variations range from room temperature to storage in liquid-nitrogen according to individual project needs.

Standard **testing for infectious diseases** includes CE marked test systems for HIV I/II antibodies, p24 antigen, HBs antigen, HCV antibodies. Tailored testing may include FDA approved assays, further analytes like HTLV or different test systems (antibody testing, NAT, ...) e.g.

**Delivery** is carried out according to demands of customer's projects and samples. This includes just in time delivery and may include delivery at specified day or even night times, delivery at various locations at the same time, verifiable temperature control, delivery on customer's account e.g.

All donation centers and cooperation partners are audited on a regular basis. in.vent explicitly welcomes to be audited by customers.

**The complexity of your requirements is our standard**

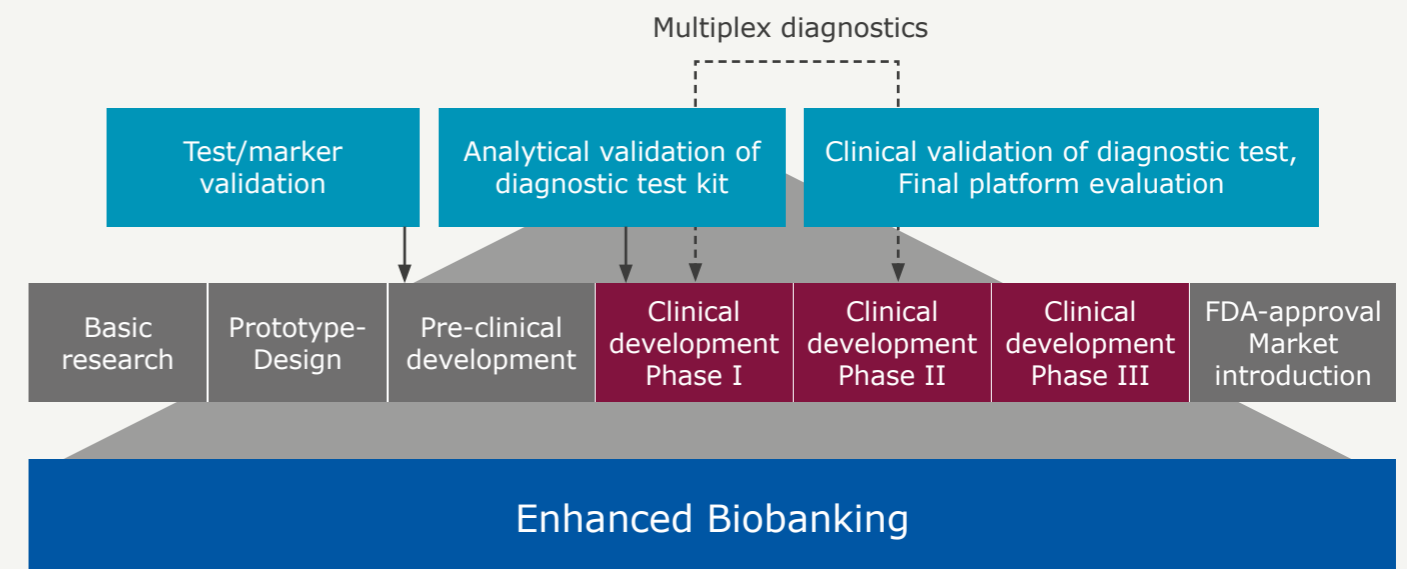
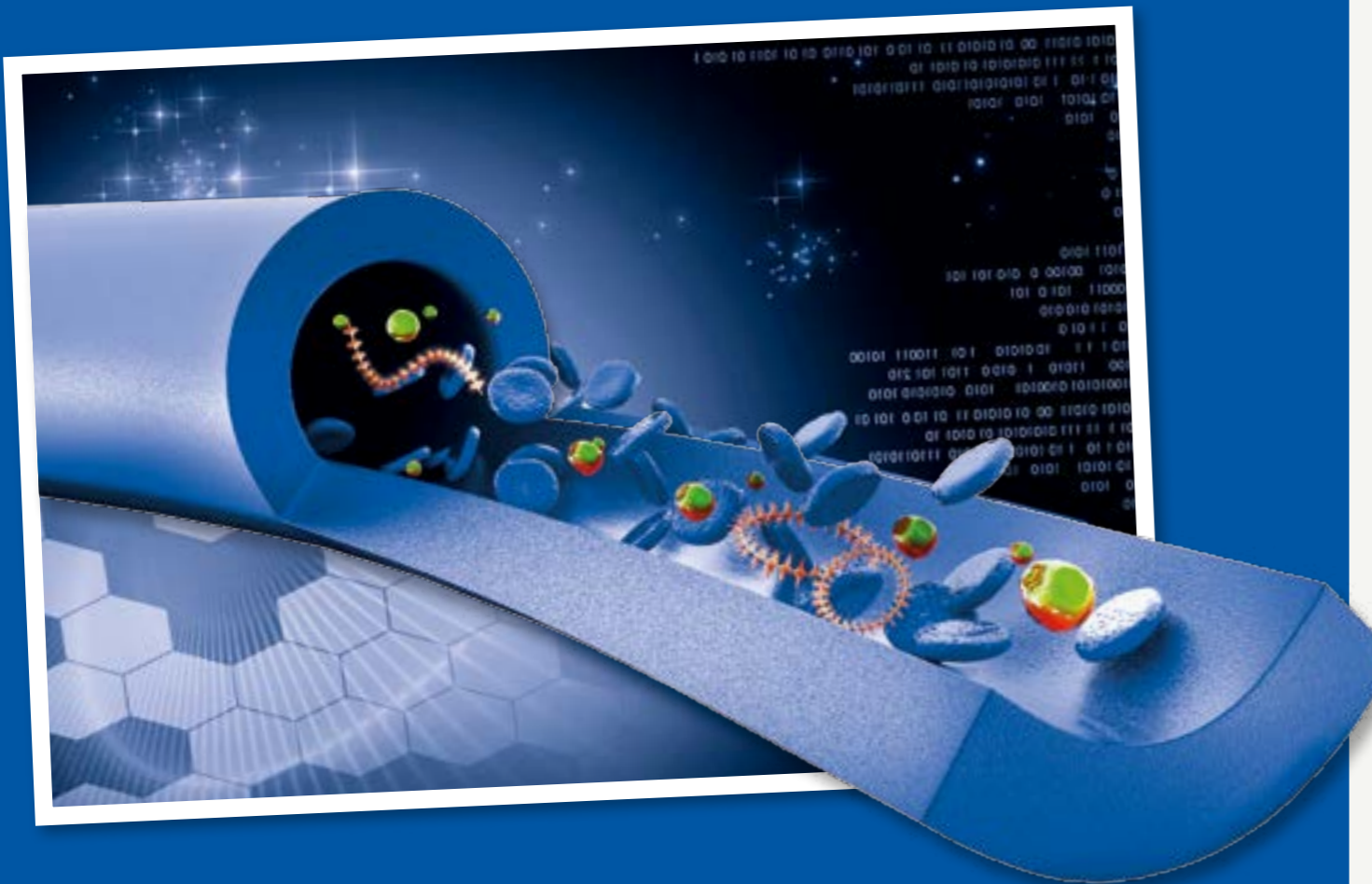
# Human Biomaterials Enhanced Biobanking®

in.vent unique approach of Enhanced Biobanking® takes into consideration that the key prerequisites for successful development of diagnostics are patients samples with reliable clinical data and highest possible quality exactly fitting to production scheme and value chain of IVDs.

The odds of already existing biobanks are that they are not harmonisable<sup>1</sup> due to huge variations regarding preanalytics, donating and processing schemes.

Enhanced Biobanking® takes these odds into consideration and guarantees customized samples in accordance with customer's requirements.

- Y just in time and predictable delivery of samples
- YYY well known preanalytics
- YYY adequate handling
- YYY volumes and titers of analytes exactly fitting to customer's needs
- YYY target oriented procurement
- YYY legally and ethically impeccable conduct and sourcing of samples
- YYY clinical information and known therapies in various levels of detail adapted to project requirements



modified according to Philipps et al. Nature Reviews, Drug Discovery 2006

<sup>1</sup> M. Neumaier  
Biobanking Infrastructures: Network for future biomedical research  
IFCC Worldlab 2011, Berlin, EMD C-CMBC Symposium

IFCC-Abbott Award 2011 for  
Significant Contributions in Molecular Diagnostics

# Diagnostic Clinical Studies



- Performance Evaluation
- Therapeutic Drug Monitoring
- Liquid Biopsies
- Regulatory/Registration

Exact and accurate conducted diagnostic clinical studies are key for registration, evaluation and improvement of diagnostics test kits.

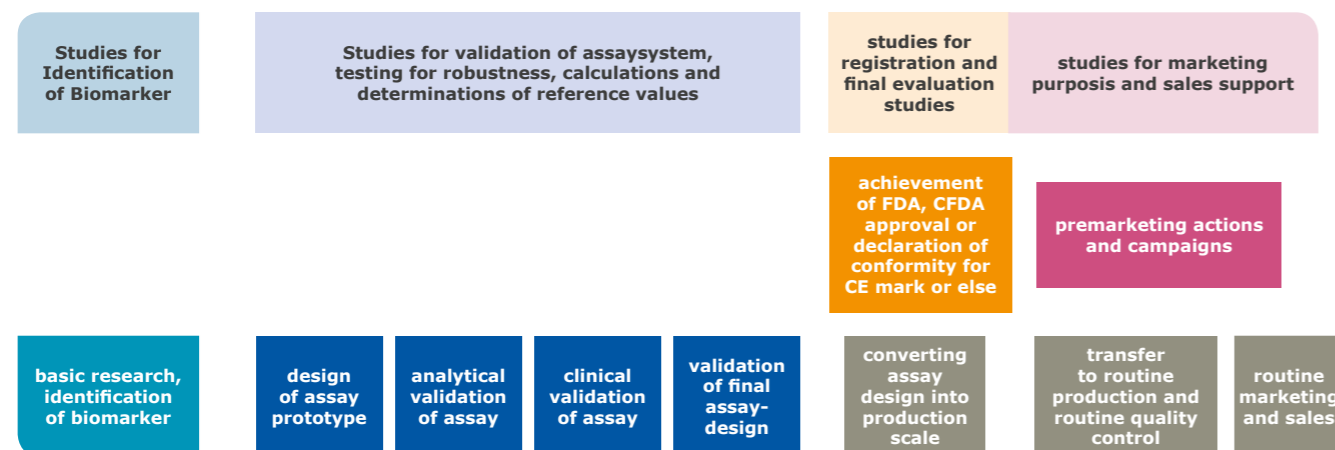
Producers of IVDs are responsible for accordance with respective registrations in their countries. Therefore studies for registration and evaluation shall prove conformity with all legal requirements. Reliability of the results, also safety for patients and users is mandatory. This has to be proven by appropriate data.

The essential prerequisite for these topics is the availability of human samples.

[in.vent](#) as Europe's leading specialist for procurement of high class human materials conducts Diagnostic Clinical Studies since 10 years in Europe and – new – in Asia. These studies cover the whole value chain of IVDs and meet exactly the requirements of customer's projects.

Ethical correct procurement of samples is guaranteed by [in.vent](#)'s strict ethical values and principles which are in accordance with all applying national and international regulations.

## Diagnostic Clinical Studies in the Context of an IVD Value Chain



[in.vent](#) conducts Clinical Studies for the following purposes:

- basic research and identification of new biomarkers
- design of assays and assay prototypes
- analytical validation of assays
- clinical validation of assays
- validation of final assay design
- performance evaluation
- converting assay prototypes into production scale
- transfer to routine production
- marketing and sales needs (benchmarking)
- therapeutic drug monitoring
- and furthermore studies conducted exactly according to customer's needs

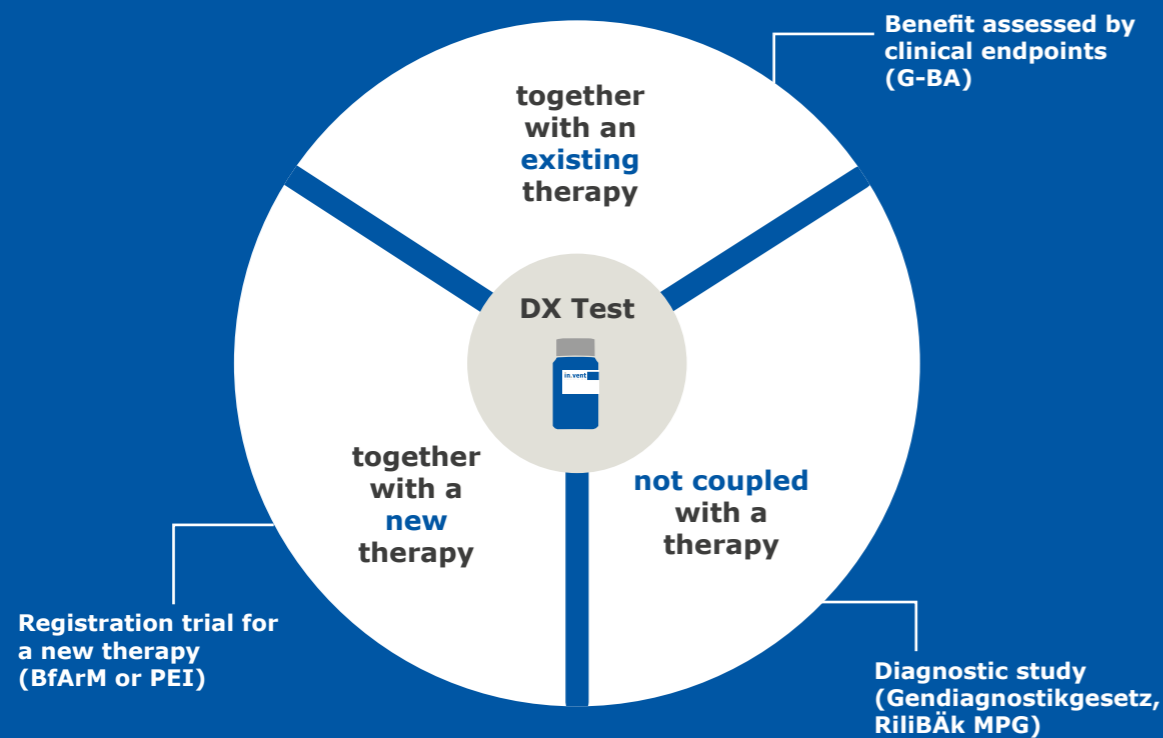
Clinical Studies conducted by [in.vent](#) find their application not only across the value chain of IVDs but as well in personalized medicine. E.g. in the evaluation of responders and non responders to designated drugs and therapies, implementation of therapeutic drug monitoring, etc.

Studies conducted by [in.vent](#) include – according to customer's needs- full services of:

- study design
- approvals of ethics committees and review boards
- identification of patients and their information
- procurement of samples
- laboratory analyses
- statistical evaluations, bio-statistics
- delivery of data

The spectrum of samples especially provided for Clinical Studies ranges from patient samples with or without detailed information exactly fitting to the project to samples useable for liquid biopsies: pairs of samples - e.g. biopsies plus corresponding blood samples.

Diagnostic Studies conducted by in.vent cover CDx (Companion Diagnostics) as well.



**Example of a Time Line for Invasive Donations with extra Volumes or Targeted Donations**

<b>Feasibility and Lead Time for requiring samples:</b>	1 - 4 weeks
<b>Study Design, Study Protocol, Assignment of Contracts:</b>	4 - 6 weeks
<b>Ethical Vote:</b>	8 - 12 weeks
<b>Recruitment of Donors, Procurement of Samples:</b>	depending on expenditure and prevalence rate of required samples: immediate delivery up to long term projects
<b>Data Management:</b>	2 weeks
<b>Biostatistical Evaluation:</b>	1 - 2 weeks
<b>Final Transfer of Data and Samples:</b>	1 week

Product number	Indication
1.1CS	customized specifications*

\* "customized specifications" are specifications exclusively derived by customers projects. Please send specifications for an individualized offer.

## 2

# Quality Control

**in.vent** Quality Controls are designed for the use in quality control in clinical diagnostic laboratories according to the RILIBÄK (Richtlinie der Bundesärztekammer zur Qualitätssicherung laboratoriumsmedizinischer Untersuchungen) and most of them are CE marked. They are used as well in Quality Control as in R&D Departments.

They consist of native human sera without additives, unless other processings are agreed to. Individually developed Quality Controls are processed according to detailed customer's requirements. They are useable for proficiency testing/EQUAS as well.

## Standard Quality Controls in.QualiCheck<sup>s</sup>

<b>Intended Use</b>	<b>in.vent Standard Quality Controls in.QualiCheck<sup>s</sup></b> are designed for the use in quality control in clinical diagnostic laboratories and Quality Control or R&D Departments. They are to be used to solve tasks of precision, accuracy or correctness of diagnostic assay measurements throughout the whole value chain of diagnostic test kits or assays. They are used to control performances of laboratory routine testing, new test methods or new equipment as well as for testing of sensitivity/specificity.	
<b>Matrix</b>	true native human serum off the clot	
<b>Volume per Sample</b>	1 ml	
<b>Constitution of Sample</b>	lyophilized	
<b>Reconstitution</b>	with 1 ml deionised water	
<b>Sample Presentation</b>	barcoded glass tubes	
<b>Product Presentation</b>	100 samples sorted in storage box	
<b>Disease State Testing</b>	tested by CE marked test systems and found negative for HIV I/II antibodies, p24 antigen, HBs antigen, HCV antibodies	
<b>Storage</b>	room temperature (15-25 °C)	
<b>Delivered Information on Certificate</b>	product number, matrix, volume, measured laboratory titers, assay system, minimum shelf life, result of infectious disease testing	
<b>Additional delivered Information</b>	instruction for reconstitution	
<b>Delivery</b>	at ambient temperatures	
<b>Glass Tubes</b>	screw top vials, 5 ml, 40 x 17.4/1.2 GL14, Fiolax transparent	
<b>Storage Box</b>	white, moisture resistant, useable for long term storage, freezable at -80 °C, 142 mm x 142 mm x 100 mm, lid provided	
Product number	Indication	Included Laboratory Markers
QC 2.1.1	Thyroid autoimmune diseases – (Graves'/Hashimoto's diseases)	TSH receptor ab (TRAb), thyroglobulin ab (a-Tg), anti thyroid peroxidase ab (a-TPO)
QC 2.1.2	Systemic Inflammation and Sepsis	C-reactive protein (CRP) and procalcitonin (PCT)
QC 2.1.3	Diabetes mellitus Type I	glutamic acid decarboxylase autoantibodies (GADA), tyrosine phosphatase autoantibodies (IA2A), islet cell antibodies (ICA), insulin autoantibodies (IAA)
QC 2.1.4	Rheumatoid Arthritis	rheumatoid factor (RF), cyclic citrullinated peptides ab (anti CCP), C-reactive protein (CRP)
QC 2.1.5	Celiac Disease	endomysial ab (IgA), gliadin ab (IgG, IgA), tissue transglutaminase ab (anti TG IgG, IgA)

## Individual Quality Controls in.QualiCheck<sup>i</sup>

<b>Intended Use</b>	<b>in.vent Individual Quality Controls in.QualiCheck<sup>i</sup></b> are produced according to detailed customer requirements and useable for kit internal and kit external controls as well as for proficiency testing.
<b>Matrix</b>	choice of all matrices, native samples, spiked samples
<b>Volume per Vial</b>	volumes start at 0.2 ml
<b>Constitution of Sample</b>	fresh samples, liquid frozen or lyophilized
<b>Sample Presentation</b>	OEM production according to requirements: labeled or unlabeled
<b>Disease State Testing</b>	CE marked assay systems or FDA approved assay systems
<b>Storage</b>	according to constitution of sample
<b>Delivery</b>	ambient temperatures, blue ice, dry ice, with or without temperature monitoring systems
<b>Vials</b>	cryotubes, glass tubes, bottles, choice of many coloured caps
<b>Packaging</b>	storage boxes, bulks, labelled or unlabelled
<b>Included Laboratory Markers, Details of Certification</b>	according to customer's requirements

Product number	Indication	Product number	Indication
QC 2.2.1	Autoimmunity	QC 2.2.6	Oncology
QC 2.2.2	Cardiac Marker	QC 2.2.7	Pregnancy/Fertility
QC 2.2.3	Clinical Chemistry	QC 2.2.8	Therapeutics
QC 2.2.4	Hormones	QC 2.2.9	Urine
QC 2.2.5	Infectious Diseases	QC 2.2.CS	customized specifications* - Proficiency Testing Quality

\* "customized specifications" are specifications exclusively derived by customers projects. Please send specifications for an individualized offer.



## 3

# Protein Chemistry

in.vent Panels of Pregnancy and Fertility – Disease State are designed for use in R&D and Quality Control Departments. They are used to control performances of laboratory routine testing, new test methods or new equipment as well as for testing of sensitivity/specificity and to evaluate cut offs or normal ranges.

## Antibodies mc anti- TSH Receptor Antibody

<b>Intended Use and Content</b>	The anti-TSH receptor antibody is competing with TSH hormone during the binding to the TSH receptor. The mc anti-TSH receptor antibody MIS 3 by in.vent is useful for ELISAs which detect TSH-receptor antibodies. All products are for research or manufacturing purposes only, and are not for use in human therapeutic procedures.
<b>Reactivity</b>	human, porcine
<b>Host</b>	mouse
<b>Clonality</b>	monoclonal
<b>Purification Process</b>	chromatography
<b>Purity</b>	> 95 %
<b>Presentation of Product</b>	liquid, in PBS buffer, pH 7.4, addition of sodium acid
<b>Stability</b>	24 months
<b>Short Term Storage</b>	2 - 8 °C,
<b>Long Term Storage</b>	-20 °C
<b>Delivered Information on Certificate</b>	product number, lot number, volume, concentration, minimum shelf life
<b>Delivery</b>	on dry ice

Product number	Trade name	
PC 3.1.1	mc anti- TSH Receptor Antibody MIS3	synthetic peptid of the human TSH binding site
PC 3.1.2	mc anti- TSH Receptor Antibody MIS5	synthetic peptid of the human intercellular domain

## Antibodies Human rec. TSH Receptor

<b>Intended Use and Content</b>	The TSH receptor is a receptor of the thyroid gland, binded by protein G. It is activated and stimulated in the context of the thyrotropic feedback control and therefore activates the secretion of T3 and T5. The in.vent rec. TSH receptor is useful for ELISAs which detect TSH receptor autoantibodies.
<b>Gen ID</b>	7253
<b>UniProt</b>	P16473
<b>Type of Protein</b>	recombinant
<b>Cell Line</b>	human, K562
<b>Purification</b>	cell disruption, no further purification
<b>Presentation of Product</b>	liquid, addition of BSA and sodium acid
<b>Stability</b>	24 months
<b>Storage</b>	< -18 °C
<b>Delivered Information on Certificate</b>	product number, lot number, volume, concentration, minimum shelf life
<b>Delivery</b>	on dry ice

Product number	Trade name
PC 3.2.1	MIS TSH-R

## Antibodies Purified rec. Protein Heterogeneous nuclear ribonucleoprotein B1 (hnRNP B1)

<b>Intended Use and Content</b>	hnRNP B1 is a 37kDa RNA-binding protein that is produced by alternative splicing. In association with pre-mRNA hnRNP B1 is localized in the nucleus of most tissues influencing mRNA processing and the nucleo-cytoplasmic transport of mRNA. Elevated hnRNP B1 levels were currently correlated with lung cancer. All products are for research or manufacturing purposes only, and are not for use in human therapeutic procedures
<b>Source</b>	expression by E. coli
<b>Purity</b>	> 95 % by SDS-PAGE
<b>Purification</b>	chromatography
<b>Analysis</b>	protein concentration using Pierce BCA
<b>Presentation of Product</b>	lyophilized, phosphate/ glycerol buffer
<b>Stability</b>	6 months
<b>Storage</b>	-20 °C
<b>Delivered Information on Certificate</b>	product number, lot number, volume, concentration, minimum shelf life
<b>Delivery</b>	on dry ice

Product number	Trade name
PC 3.2.2	hnRNP B1

# Human Biomaterials

## Disease State

### Autoimmune Disease

# 4

**in.vent** Panels of Disease State Donors are designed to be used to control performances of laboratory routine testing, new test methods or new equipment as well as for testing of sensitivity/specificity and to evaluate cut offs or normal ranges in R&D or Quality Control Departments. They consist of native samples without additives.

#### Panels of Autoimmune Biomarkers

<b>Intended Use</b>	The <b>in.vent Panels of Autoimmune Biomarkers</b> are designed for the use in R&D and Quality Control departments, mainly for study schemes regarding cut offs, studies for certification. The entire range of test results is represented within the panel.
<b>Matrix</b>	true native human serum off the clot
<b>Volume per Sample</b>	0.5 ml
<b>Number of Samples per Sales Unit</b>	10
<b>Number of different Donors per Sales Unit</b>	10
<b>Constitution of Sample</b>	liquid frozen
<b>Instruction for Thawing</b>	perpendicular stored at 4 to 10 °C, gently mixing every 0.5 h
<b>Storage</b>	-22 to -18 °C
<b>Delivered Information on Certificate</b>	product number, serum number, matrix, volume, ICD10, age, gender, minimum shelf life, scheme of processing
<b>Delivery</b>	on dry ice
<b>Cryotubes</b>	volume: 0.5 ml; diameter: 10.8 mm; length: 46 mm; shape of bottom: cylindrical, conical with round stand-up edges; screw cap with rubber seal; Polypropylen; transparent; to be centrifuged up to 2,000 g; freezable down to -80 °C
<b>Storage Box</b>	white, moisture resistant, crossed compartment inserts, useable for long term storage, freezable down to -80 °C, lid provided
<b>Provided levels</b>	borderline, low, medium, high levels, extraordinary high levels

Product number	Biomarker	Product number	Biomarker
DSPA 4.1.1.1.1	anti dsDNA	DSPA 4.1.1.1.6	anti SCL70
DSPA 4.1.1.1.2	anti Centromere	DSPA 4.1.1.1.7	anti tTg IgA
DSPA 4.1.1.1.3	anti Gliadin IgA	DSPA 4.1.1.1.8	anti tTg IgG
DSPA 4.1.1.1.4	anti Gliadin IgG	DSPA 4.1.1.1.9	customized specifications* - Panels of Autoimmune Biomarkers
DSPA 4.1.1.1.5	anti La		

\* "customized specifications" are specifications exclusively derived by customers projects. Please send specifications for an individualized offer.

#### Panels of Autoimmune Diseases – ICD10

<b>Intended Use</b>	The <b>in.vent Panels of Autoimmune Diseases – ICD10</b> are designed for the use in R&D and Quality Control departments, mainly for study schemes regarding cut offs, studies for certification. The samples are not sorted according to age or gender. They consist of native samples without additives. The samples are chosen by International Classification of Disease (ICD10).
<b>Matrix</b>	true native human serum off the clot
<b>Volume per Unit</b>	0.5 ml
<b>Number of Samples per Sales Unit</b>	10
<b>Number of donors per Sales Unit</b>	10
<b>Constitution of Sample</b>	liquid frozen
<b>Instruction for Thawing</b>	perpendicular stored at 4 to 10 °C, gently mixing every 0.5 h
<b>Storage</b>	-22 to -18 °C
<b>Delivered Information in Certificate</b>	product number, serum number, matrix, volume, age, gender, minimum shelf life, scheme of processing
<b>Delivery</b>	on dry ice
<b>Cryotubes</b>	volume: 0.5 ml; diameter: 10.8 mm; length: 46 mm; shape of bottom: cylindrical, conical with round stand-up edges; screw cap with rubber seal; Polypropylen; transparent; to be centrifuged up to 2,000 g; freezable down to -80 °C
<b>Storage Box</b>	white, moisture resistant, crossed compartment inserts, useable for long term storage, freezable down to -80 °C, lid provided

Product number	Autoimmune Disease	Product number	Indication
DSPA 4.1.1.2.1	Coeliac Disease	DSPA 4.1.1.2.9	Reactive Arthritis
DSPA 4.1.1.2.2	Dermatomyositis – Polymyositis	DSPA 4.1.1.2.10	Rheumatoid Arthritis
DSPA 4.1.1.2.3	Fibromyalgia	DSPA 4.1.1.2.11	SAPHO-Syndrome
DSPA 4.1.1.2.4	Graves' Disease*	DSPA 4.1.1.2.12	Sjogren's Syndrome
DSPA 4.1.1.2.5	Hashimoto's Disease*	DSPA 4.1.1.2.13	Spondylitis ankylosans
DSPA 4.1.1.2.6	MCTD	DSPA 4.1.1.2.14	Wegener's Granulomatosis
DSPA 4.1.1.2.7	Myositis	DSPA 4.1.1.2.CS	customized specifications* - Panels of autoimmune Indications (including ICD10)
DSPA 4.1.1.2.8	PSS		

\* "customized specifications" are specifications exclusively derived by customers projects. Please send specifications for an individualized offer.

# 3

## Disease State Drugs of Abuse

**in.vent** Panels of Drugs of Abuse are intended to be used to control performances of laboratory routine testing, new test methods or new equipment as well as for testing of sensitivity/specificity and to evaluate cut offs or normal ranges in R&D or Quality Control Departements. The panels consist of native materials without additives.

### Abuse of Alcohol

#### Panels of Carbohydrate Deficient Transferrin (CDT)

<b>Intended Use</b>	The <b>in.vent Panels of CDT</b> are designed for the use in R&D and Quality Control departements, mainly for study schemes regarding cut offs, studies for certification. Carbohydrate-deficient transferrin is elevated in the blood of heavy alcoholism but raised levels can also be found in a number of medical conditions. The panel consists of 10 samples from 10 different donors, not sorted by age or gender.
<b>Matrix</b>	true native human serum off the clot
<b>Volume per Sample</b>	0.5 ml
<b>Number of Samples</b>	10
<b>Number of Donors</b>	10
<b>Constitution of Sample</b>	liquid frozen
<b>Instruction for Thawing</b>	perpendicular stored at 4 to 10 °C, gently mixing every 0.5 h
<b>Storage</b>	-22 to -18 °C
<b>Delivered Information on Certificate</b>	product number, sample number, matrix, volume, age, gender, measured laboratory results, assay system, minimum shelf life, scheme of processing
<b>Delivery</b>	on dry ice
<b>Cryotubes</b>	volume: 0.5 ml; diameter: 10.8 mm; length: 46 mm; shape of bottom: cylindrical, conical with round stand-up edges; screw cap with rubber seal; Polypropylen; transparent; to be centrifuged up to 2,000 g; freezable down to -80 °C
<b>Storage Box</b>	white, moisture resistant, crossed compartment inserts, useable for long term storage, freezable down to -80 °C, lid provided
<b>measured laboratory markers</b>	CDT measured by HPLC

Product number	Trade name
DSPA 4.1.2.1.1	CDT Panel
DSPA 4.1.2.1.1.CS	customized specifications* - Drugs of Abuse - Panel

\* "customized specifications" are specifications exclusively derived by customers projects. Please send specifications for an individualized offer.

#### Panels of Autoimmune Diseases

<b>Intended Use</b>	The <b>in.vent Panels of Autoimmune Diseases</b> are designed for the use in R&D and Quality Control departements, mainly for study schemes regarding cut offs, studies for certification. The samples are not sorted according to age or gender. They consist of native samples without additives from donors with detailed indications. The individual laboratory measurements are indicated in the certificate.
<b>Matrix</b>	true native human serum off the clot
<b>Volume per Unit</b>	0.5 ml
<b>Number of Samples per Sales Unit</b>	10
<b>Number of Donors per Sales Unit</b>	10
<b>Constitution of Sample</b>	liquid frozen
<b>Instruction for Thawing</b>	perpendicular stored at 4 to 10 °C, gently mixing every 0.5 h
<b>Storage</b>	-22 to -18 °C
<b>Delivered Information on Certificate</b>	product number, serum number, matrix, volume, age, gender, minimum shelf life, scheme of processing
<b>Delivery</b>	on dry ice
<b>Cryotubes</b>	volume: 0.5 ml; diameter: 10.8 mm; length: 46 mm; shape of bottom: cylindrical, conical with round stand-up edges; screw cap with rubber seal; Polypropylen; transparent; to be centrifuged up to 2,000 g; freezable down to -80 °C
<b>Storage Box</b>	white, moisture resistant, crossed compartment inserts, useable for long term storage, freezable down to -80 °C, lid provided

Product number	Autoimmune Disease	measured laboratory markers
DSPA 4.1.1.3.1	Coeliac Disease	anti tTg and/or anti Gliadin
DSPA 4.1.1.3.2	Rheumatoid Arthritis A	RF, anti CCP, anti CRP, IFT titer and fluorescence pattern
DSPA 4.1.1.3.3	Rheumatoid Arthritis B	RF
DSPA 4.1.1.3.4	Graves' Disease*	anti TPO, anti Tg, TRAb
DSPA 4.1.1.3.5	Hashimoto's Disease*	anti TPO, anti Tg
DSPA 4.1.1.3.CS	customized specifications* Panels of autoimmune Indications	

\* "customized specifications" are specifications exclusively derived by customers projects. Please send specifications for an individualized offer.

### Pools of Carbohydrate Deficient Transferrin (CDT)

<b>Intended Use</b>	The <b>in.vent CDT Samples – large volumes</b> are designed for the use in R&D and Quality Control departments, mainly for study schemes regarding cut offs, studies for certification. Carbohydrate-deficient transferrin is elevated in the blood of heavy alcoholism but raised levels can also be found in a number of medical conditions.
<b>Matrix</b>	true native human serum off the clot
<b>Volume per Unit</b>	50 ml
<b>Number of Samples</b>	1
<b>Number of Donors</b>	10
<b>Constitution of Sample</b>	liquid frozen
<b>Instruction for Thawing</b>	perpendicular stored at 4 to 10 °C, gently mixing every 0.5 h
<b>Storage</b>	-22 to -18 °C
<b>Delivered Information in Certificate</b>	product number, sample number, matrix, volume, age, gender, measured laboratory results, assay system, minimum shelf life, scheme of processing
<b>Delivery</b>	on dry ice
<b>Bottle</b>	volume 50 ml, white, translucent, polypropylen low density (LDPE), freezable down to -30 °C
<b>measured laboratory markers</b>	CDT measured by HPLC

Product number	Trade name
DSPA 4.1.2.1.2	CDT Pool
DSPA 4.1.2.1.2.CS	customized specifications* - Drugs of Abuse - Pool

\* "customized specifications" are specifications exclusively derived by customers projects. Please send specifications for an individualized offer.

### Panels of Carbohydrate Deficient Transferrin (CDT) – Urine with corresponding Serum

<b>Intended Use</b>	The <b>in.vent Panels of CDT – Urine with corresponding Serum</b> are designed for the use in R&D departments, mainly for study schemes regarding new biomarkers for abuse of alcohol or other conditions.
<b>Matrix</b>	true native human serum off the clot
<b>Volume per Unit</b>	10 ml
<b>Number of Samples</b>	10 x urine + 10 x serum
<b>Number of Donors</b>	10
<b>Volume per Sales Unit</b>	100 ml urine (10 x 10 ml) + 100 ml serum (10 x 10 ml)
<b>Constitution of Sample</b>	liquid frozen
<b>Instruction for Thawing</b>	perpendicular stored at 4 to 10 °C, gently mixing every 0.5 h
<b>Storage</b>	-22 to -18 °C
<b>Delivered Information on Certificate</b>	product number, sample number, matrix, volume, age, gender, measured laboratory results, assay system, minimum shelf life, scheme of processing
<b>Delivery</b>	on dry ice
<b>Bottle</b>	volume 100 ml, white, translucent, polypropylen low density (LDPE), freezable down to -30 °C
<b>measured laboratory markers</b>	CDT measured by HPLC

Product number	Trade name
DSPA 4.1.2.1.3	CDT Urine & Serum
DSPA 4.1.2.1.3.CS	customized specifications* - Drugs of Abuse - Urine & Serum

\* "customized specifications" are specifications exclusively derived by customers projects. Please send specifications for an individualized offer.

## 4

# Disease State Diabetes I/II

**in.vent** Panels of Diabetes I/II are designed to be used to control performances of laboratory routine testing, new test methods or new equipment as well as for testing of sensitivity/specificity and to evaluate cut offs or normal ranges in R&D or Quality Control Departments. The panels consist of native materials without additives.

## Panels of Biomarkers for Diabetes I

<b>Intended Use and Content</b>	The <b>in.vent</b> Panels of Diabetes I are designed for the use in R&D and Quality Control departments, mainly for study schemes regarding cut offs or studies for certification. The panel consists of 10 samples from 10 different donors, not sorted by age or gender. The levels cover the entire measurement range of routine assays.
<b>Matrix</b>	true native human serum off the clot
<b>Volume per Sample</b>	0.5 ml
<b>Number of Samples per Sales Unit</b>	10
<b>Number of different Donors per Sales Unit</b>	10
<b>Constitution of Sample</b>	liquid frozen
<b>Instruction for Thawing</b>	perpendicular stored at 4 to 10 °C, gently mixing every 0.5 h
<b>Storage</b>	-22 to -18 °C
<b>Delivered Information on Certificate</b>	product number, sample number, matrix, volume, age, gender, measured laboratory results, assay system, minimum shelf life, scheme of processing
<b>Delivery Cryocubes</b>	on dry ice volume: 0.5 ml; diameter: 10.8 mm; length: 46 mm; shape of bottom: cylindrical, conical with round stand-up edges; screw cap with rubber seal; Polypropylen; transparent; to be centrifuged up to 2,000 g; freezable down to -80 °C
<b>Storage Box</b>	white, moisture resistant, crossed compartment inserts, useable for long term storage, freezable down to -80 °C, 142 mm x 142 mm x 100 mm, lid provided
<b>Provided levels</b>	borderline, low, medium, high levels, extraordinary high levels

Product number	Biomarker
DSPA 4.1.3.1.1	Insulin ab (IAA)
DSPA 4.1.3.1.2	Iceland cell ab (ICA)
DSPA 4.1.3.1.3	Tyrosine-Phosphatase ab (IA2)
DSPA 4.1.3.1.4	Glutamate-Decarboxylase ab (GADA)

## Panels of Biomarkers for Diabetes II

<b>Intended Use and Content</b>	The <b>in.vent</b> Panels of Biomarkers for Diabetes II are designed for the use in R&D and Quality Control departments, mainly for study schemes regarding cut offs, studies for certification. The panel consists of 10 samples from 10 different donors, not sorted by age or gender. The levels cover the entire measurement range of routine assays.
<b>Volume per Sample</b>	0.5 ml
<b>Number of Samples per Sales Unit</b>	10
<b>Number of Donors per Sales Unit</b>	10
<b>Constitution of Sample</b>	liquid frozen
<b>Instruction for Thawing</b>	perpendicular stored at 4 to 10 °C, gently mixing every 0.5 h
<b>Storage</b>	-22 to -18 °C
<b>Delivery Cryotubes</b>	on dry ice volume: 0.5 ml; diameter: 10.8 mm; length: 46 mm; shape of bottom: cylindrical, conical with round stand-up edges; screw cap with rubber seal; Polypropylen; transparent; to be centrifuged up to 2,000 g; freezable down to -80 °C
<b>Storage Box</b>	white, moisture resistant, crossed compartment inserts, useable for long term storage, freezable down to -80 °C, lid provided

Product number	Trade name	Matrix
DSPA 4.1.3.1.5	customized specifications* - Panels of Diabetes I	EDTA whole blood
DSPA 4.1.3.1.6	HbA1c EDTA whole blood	Serum
DSPA 4.1.3.1.7	HbA1c Serum	Urine
DSPA 4.1.3.1.8	Glucosuria Urine	
DSPA 4.1.3.1.CS	customized specifications* - Panels of Diabetes II	

\* "customized specifications" are specifications exclusively derived by customers projects. Please send specifications for an individualized offer.



**Panels of Diabetes Diseases**

<b>Intended Use and Content</b>	The <b>in.vent Panels of Diabetes</b> are designed for the use in R&D and Quality Control departments, mainly for study schemes regarding cut offs, studies for certification. The panel consists of 10 samples from 10 different donors, not sorted by age or gender. The samples are characterized by International Classification of Disease (ICD10). Further information include patients condition, age, gender, height, weight and medication.
<b>Matrix</b>	true native human serum off the clot
<b>Volume per Sample</b>	0.5 ml
<b>Number of Samples per Sales Unit</b>	10
<b>Number of Donors per Sales Unit</b>	10
<b>Constitution of Sample</b>	liquid frozen
<b>Instruction for Thawing</b>	perpendicular stored at 4 to 10 °C, gently mixing every 0.5 h
<b>Storage</b>	-22 to -18 °C
<b>Delivered Information on Certificate</b>	product number, sample number, matrix, volume, age, gender, measured laboratory results, assay system, minimum shelf life, scheme of processing
<b>Transportation</b>	on dry ice
<b>Cyrocubes</b>	volume: 0.5 ml; diameter: 10.8 mm; length: 46 mm; shape of bottom: cylindrical, conical with round stand-up edges; screw cap with rubber seal; Polypropylen; transparent; to be centrifuged up to 2,000 g; freezable down to -80 °C
<b>Storage Box</b>	white, moisture resistant, crossed compartment inserts, useable for long term storage, freezable down to -80 °C, lid provided

Product number	Trade name
DSPA 4.1.3.2.1	Panel Diabetes Type I
DSPA 4.1.3.2.2	Panel Diabetes Type II
DSPA 4.1.3.2.3	Panel selected medication
DSPA 4.1.3.2.CS1	customized specifications* - Indications - Diabetes I
DSPA 4.1.3.2.CS2	customized specifications* - Indications - Diabetes II

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# Disease State Infectious Diseases

**in.vent** Samples and Panels of Infeciology are patient samples tested for designated infectious diseases. They are either positive or negative. The intire range of test results is represented within the panel. Titers will vary accoring to availability of samples. They are designed to be used in R&D and Qualtiy Control Departements. They are to be used to differentiate normal population/cohorts with normal levels of analytes from patients with elevated levels and are used to control performances of laboratory routine testing, new test methods or new equipment as well as for testing of sensitivity/specificity and to evaluate cut offs or normal ranges.

**Panels of patient serum samples tested positive for Infectious Diseases**

<b>Intended Use and Content</b>	<b>in.vent Patient Samples of Infeciology are clinical samples tested positive for designated infectious diseases.</b> They are designed to be used in R&D and Qualtiy Control Departements. They are to be used to differentiate normal population/cohorts with normal levels of analytes from patients with elevated levels and are used to control performances of laboratory routine testing, new test methods or new equipment as well as for testing of sensitivity/specificity and to evaluate cut offs or normal ranges. The panels consist of native materials with no additives.
<b>Matrix</b>	true native human serum off the clot
<b>Volume per Sample</b>	0.5 ml
<b>Number of Samples per Sales Unit</b>	according to customer´s specifications
<b>Number or Samples per Level</b>	according to customer´s specifications
<b>Number of Levels</b>	according to customer´s specifications
<b>Number of different Donors</b>	according to customer´s specifications
<b>Constitution of Sample</b>	liquid frozen
<b>Instruction for Thawing</b>	perpendicular stored at 4 to 10 °C, gently mixing every 0.5 h
<b>Sample Presentation</b>	barcoded cryotubes
<b>Product Presentation</b>	samples sorted in storage box
<b>Storage</b>	-22 to -18 °C
<b>Delivered Information on Certificate</b>	product number, sample number, matrix, volume, age, gender, measured laboratory results, assay system, minimum shelf life, scheme of processing
<b>Delivery</b>	on dry ice
<b>Cyrocubes</b>	volume: 0.5 m; diameter: 10.8 mm; length: 46 mm; shape of bottom: cylindrical, conical with round stand-up edges; screw cap with rubber seal; Polypropylen; tranparent; to be centrifuged up to 2,000 g; freezable down to -80 °C
<b>Storage Box</b>	white, moisture resistant, crossed compartment inserts, useable for long term storage, freezable down at -80 °C, lid provided

Product number	Biomarker	Product number	Biomarker
DSPA 4.1.4.1.1	Cytomegalovirus IgG (CMV IgG)	DSPA 4.1.4.1.17	Herpes simplex virus 1 IgM (HSV 1 IgM)
DSPA 4.1.4.1.2	Cytomegalovirus IgM (CMV IgM)	DSPA 4.1.4.1.18	Herpes simplex virus 2 IgG (HSV 2 IgG)
DSPA 4.1.4.1.3	Chlamydia pneumoniae IgA	DSPA 4.1.4.1.19	Herpes simplex virus 2 IgM (HSV 2 IgM)
DSPA 4.1.4.1.4	Chlamydia pneumoniae IgG	DSPA 4.1.4.1.20	Human L Lymphotropic Virus (HTLV)
DSPA 4.1.4.1.5	Chlamydia pneumoniae IgM	DSPA 4.1.4.1.21	Malaria
DSPA 4.1.4.1.6	Chlamydia trachomatis IgA	DSPA 4.1.4.1.22	Measles
DSPA 4.1.4.1.7	Chlamydia trachomatis IgG	DSPA 4.1.4.1.23	Mycoplasma pneumoniae
DSPA 4.1.4.1.8	Chlamydia trachomatis IgM	DSPA 4.1.4.1.24	Parvovirus B19
DSPA 4.1.4.1.9	Epstein Barr Virus IgG (EBV IgG)	DSPA 4.1.4.1.25	Rubella IgG
DSPA 4.1.4.1.10	Epstein Barr Virus IgM (EBV IgM)	DSPA 4.1.4.1.26	Rubella IgM
DSPA 4.1.4.1.11	Helicobacter pylori IgG	DSPA 4.1.4.1.27	Syphilis (TPA)
DSPA 4.1.4.1.12	Helicobacter pylori IgM	DSPA 4.1.4.1.28	Toxoplasma IgG
DSPA 4.1.4.1.13	Hepatitis B surface antigen (HBsAG)	DSPA 4.1.4.1.29	Toxoplasma IgM
DSPA 4.1.4.1.14	Hepatitis B core antibody IgM	DSPA 4.1.4.1.CS	customized specifications* - Infectiology - Serum
DSPA 4.1.4.1.15	Hepatitis C IgG (HCV IgG)		
DSPA 4.1.4.1.16	Herpes simplex virus 1 IgG (HSV 1 IgG)		

**Panels of patient plasma samples tested positive for Infectious Diseases**

<b>Intended Use and Content</b>	<b>in.vent</b> Patient Plasma Samples of Infeciology are clinical samples tested positive for designated infectious diseases. They are designed to be used in R&D and Quality Control Departements. They are to be used to differentiate normal population/cohorts with normal levels of analytes from patients with elevated levels and are used to control performances of laboratory routine testing, new test methods or new equipment as well as for testing of sensitivity/specificity and to evaluate cut offs or normal ranges. The panels consist of native materials with no additives.
<b>Matrix</b>	Plasma
<b>Volume per Sample</b>	0.5 ml up to customer´s requirements
<b>Number of Samples per Sales Unit</b>	according to customer´s specifications
<b>Number of different Donors</b>	according to customer´s specifications
<b>Constitution of Sample</b>	according to customer´s specifications
<b>Instruction for Thawing</b>	according to customer´s specifications
<b>Sample Presentation</b>	barcoded cryotubes
<b>Product Presentation</b>	samples sorted in storage box
<b>Storage</b>	-22 to -18 °C
<b>Delivered Information on Certificate</b>	product number, sample number, matrix, volume, age, gender, indication, measured laboratory results, assay system, minimum shelf life, scheme of processing
<b>Delivery</b>	on dry ice
<b>Cryotubes</b>	volume: 0.5 ml; diameter: 10.8 mm; length: 46 mm; shape of bottom: cylindrical, conical with round stand-up edges; screw cap with rubber seal; Polypropylen; transparent; to be centrifuged up to 2000g; freezable down to -80 °C
<b>Storage Box</b>	white, moisture resistant, crossed compartment inserts, useable for long term storage, freezable down at -80 °C, lid provided

Product number	Biomarker
DSPA 4.1.4.2.1	CMV IgG
DSPA 4.1.4.2.2	Helicobacter pylori
DSPA 4.1.4.2.3	HBV
DSPA 4.1.4.2.4	HCV

Product number	Biomarker
DSPA 4.1.4.2.5	Rubella IgG
DSPA 4.1.4.2.6	Toxoplasma gondii
DSPA 4.1.4.2.CS	customized specifications* - Infectiology - Plasma

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## 4

# Disease State Lyme Diseases

**in.vent** Panels of Lyme Disease are designed to be used to control performances of laboratory routine testing, new test methods or new equipment as well as for testing of sensitivity/specificity and to evaluate cut offs or normal ranges in R&D or Quality Control Departments. The panels consist of native materials without additives.

## Panels of Lyme Disease

<b>Intended Use and Content</b>	The <b>in.vent Panels of Lyme Disease</b> are representative for different types of Borrelia species. The panel is intended to be used e.g. in R&D and Quality Control Departments, mainly for study schemes regarding normal ranges of titers of biomarkers. This panel includes different types off Borrelia, not sorted. Laboratory testing includes Line Blot and or ELISA testing. Each panel consists of 20 donations of different donors.
<b>Matrix</b>	true native human serum off the clot
<b>Volume per Sample</b>	0.5 ml
<b>Number of Samples per Sales Unit</b>	20
<b>Constitution of Sample</b>	liquid frozen
<b>Instruction for Thawing</b>	perpendicular stored at 4 to 10 °C, gently mixing every 0.5 h
<b>Sample Presentation</b>	barcoded cryotubes
<b>Product Presentation</b>	samples sorted in storage box
<b>Storage</b>	-22 to -18 °C
<b>Delivered Information on Certificate</b>	product number, sample number, matrix, volume, age, gender, measured laboratory results, assay system, minimum shelf life, scheme of processing
<b>Delivery</b>	on dry ice
<b>Cyrocubes</b>	volume: 0.5 ml; diameter: 10.8 mm; length: 46 mm; shape of bottom: cylindrical, conical with round stand-up edges; screw cap with rubber seal; Polypropylen; transparent; to be centrifuged up to 2,000 g; freezable down to -80 °C
<b>Storage Box</b>	white, moisture resistant, crossed compartment inserts, useable for long term storage, freezable down to -80 °C, lid provided
<b>Provided levels</b>	borderline, low, medium, high levels, extraordinary high levels

Product number	Trade name
DSPA 4.1.4.3	Lyme Disease Panel A
DSPA 4.1.4.3.CS	customized specifications* - Lyme Disease

\* "customized specifications" are spezifications exclusively derived by customers projects. Please send specifications for an individualized offer.

## Panels of Lyme Disease – Details

<b>Intended Use and Content</b>	The <b>in.vent Panels of Lyme Disease – Details</b> are representative for different Borrelia species. The panel is intended to be used e.g. in R&D and Quality Control Departments, mainly for study schemes regarding normal ranges of titers of biomarkers. It includes different types off Borrelia, not sorted. Laboratory testing includes Line Blot and or ELISA testing. In difference to Lyme Disease Panel A the information about the patient is much more detailed and includes information regarding symptoms like Erythema migrans, time between tick bite, initial diagnosis and medication. Each panel consists of 20 donations of different donors.
<b>Matrix</b>	true native human serum off the clot
<b>Volume per Sample</b>	0.5 ml
<b>Number of Samples per Sales Unit</b>	20
<b>Constitution of Sample</b>	liquid frozen
<b>Instruction for Thawing</b>	perpendicular stored at 4 to 10 °C, gently mixing every 0.5 h
<b>Sample Presentation</b>	barcoded cryotubes
<b>Product Presentation</b>	samples sorted in storage box
<b>Storage</b>	-22 to -18 °C
<b>Delivered Information on Certificate</b>	product number, sample number, matrix, volume, age, gender, measured laboratory results, assay system, anamnesis, symptoms, medication, minimum shelf life, result of infectious disease testing, scheme of processing
<b>Delivery</b>	on dry ice
<b>Cryotubes</b>	volume: 0.5 ml; diameter: 10.8 mm; length: 46 mm; shape of bottom: cylindrical, conical with round stand-up edges; screw cap with rubber seal; Polypropylen; transparent; to be centrifuged up to 2,000 g; freezable down to -80 °C
<b>Storage Box</b>	white, moisture resistant, crossed compartment inserts, useable for long term storage, freezable down to -80 °C, lid provided

Product number	Trade name
DSPA 4.1.4.4	Lyme Disease Panel B
DSPA 4.1.4.4.CS	customized specifications* - Lyme Disease (including detailed data)

\* "customized specifications" are spezifications exclusively derived by customers projects. Please send specifications for an individualized offer.



## 4

# Disease State

## Sepsis - Procalcitonin (PCT)

**in.vent** Panels of Sepsis/PCT are intended to be used to differentiate normal population/cohorts with normal levels of analytes from patients. The panels are used to control performances of laboratory routine testing, new test methods or new equipment as well as for testing of sensitivity/specificity and to evaluate cut offs or normal ranges in R&D or Quality Control Departments. PCT is used for the diagnosis of bacterial infections and indicates complications arising from systemic inflammations. PCT stays within the normal range up to low levels at viral or autoimmune diseases, malignancies, allergic reactions as well as at local infections. It is expressed by the systemic influence of bacterial endotoxins and in many cases of systemic fungal infections accompanied by severe systemic inflammations. High titers are found as well in plasma as in serum of patients suffering from malaria e.g.

### Panels of native PCT – small volumes

<b>Intended Use and Content</b>	The <b>in.vent Panels of PCT – small volumes</b> are intended for the use in R&D and Quality Control departments, mainly for study schemes regarding cut offs or studies for certification. The range of titers of samples cover the entire range of values of measurements of routine assays. The panel consists of 10 samples from 10 different donors.
<b>Matrix</b>	true native human serum off the clot
<b>Volume per Sample</b>	0.2 ml
<b>Number of Samples per Sales Unit</b>	10
<b>Number of different Donors</b>	10
<b>Constitution of Sample</b>	liquid frozen
<b>Instruction for Thawing</b>	perpendicular stored at 4 to 10 °C, gently mixing every 0.5 h
<b>Storage</b>	-22 to -18 °C
<b>Delivered Information on Certificate</b>	product number, sample number, matrix, volume, age, gender, minimum shelf life, scheme of processing
<b>Delivery Cryocubes</b>	on dry ice volume: 0.5 ml; diameter: 10.8 mm; length: 46 mm; shape of bottom: cylindrical, conical with round stand-up edges; screw cap with rubber seal; Polypropylen; transparent; to be centrifuged up to 2,000 g; freezable down to -80 °C
<b>Storage Box</b>	white, moisture resistant, crossed compartment inserts, useable for long term storage, freezable down to -80 °C, lid provided

Product number	Trade name	Provided Information
DSPA 4.1.5.1.1	PCT1	Titer of PCT
DSPA 4.1.5.1.1.CS	customized specifications* - Sepsis - native PCT	

\* "customized specifications" are specifications exclusively derived by customers projects. Please send specifications for an individualized offer.

### Panels of native PCT – consecutive donations

<b>Intended Use</b>	The <b>in.vent Panels of PCT – consecutive donations</b> are designed for the use in R&D and Quality Control departments, mainly for study schemes regarding cut offs, studies for certification. The panel consists of all consecutive donations from 1 donor. The number of samples differ from panel to panel. Minimum number of consecutive donations is 3. Detailed information are given before delivery.
<b>Matrix</b>	true native human serum off the clot
<b>Volume per Sample</b>	0.2 ml
<b>Number of Samples per Sales Unit</b>	minimum 3
<b>Number of Donors</b>	1
<b>Constitution of Sample</b>	liquid frozen
<b>Instruction for Thawing</b>	perpendicular stored at 4 to 10 °C, gently mixing every 0.5 h
<b>Storage</b>	-22 to -18 °C
<b>Delivered Information on Certificate</b>	product number, sample number, matrix, volume, age, gender, measured laboratory markers, assay system, minimum shelf life, scheme of processing, further information see provided information
<b>Delivery Cryotubes</b>	on dry ice volume: 0.5 ml; diameter: 10.8 mm; length: 46 mm; shape of bottom: cylindrical, conical with round stand-up edges; screw cap with rubber seal; Polypropylen; transparent; to be centrifuged up to 2,000 g; freezable down to -80 °C
<b>Storage Box</b>	white, moisture resistant, crossed compartment inserts, useable for long term storage, freezable down to -80 °C, lid provided

Product number	Trade name	Provided Information
DSPA 4.1.5.1.2	PCT2	date of donations, Titer of PCT, ICD10, appropriate Disease Score(s), anamnesis, clinical details, all measured laboratory values, medication, age, gender
DSPA 4.1.5.1.2.CS	customized specifications* - Sepsis - native PCT (including detailed data)	

\* "customized specifications" are specifications exclusively derived by customers projects. Please send specifications for an individualized offer.

**Samples of native PCT – large volumes**

<b>Intended Use</b>	The <b>in.vent Panels of native PCT</b> are designed for the use in R&D and Quality Control departments, mainly for study schemes regarding cut offs, studies for certification and production purposes. One sample consists of all the volume that was donated in one donation of one patient. The volume of samples may differ. The minimum volume is 3 ml.
<b>Matrix</b>	true native human serum off the clot
<b>Volume per Sample</b>	minimum 3 ml
<b>Number of Samples per Sales Unit</b>	1
<b>Number of Donors</b>	1
<b>Constitution of Sample</b>	liquid frozen
<b>Instruction for Thawing</b>	perpendicular stored at 4 to 10 °C, gently mixing every 0.5 h
<b>Storage</b>	-22 to -18 °C
<b>Delivered Information on Certificate</b>	product number, sample number, matrix, volume, age, gender, measured laboratory markers, assay system, minimum shelf life, scheme of processing, further information see provided information
<b>Delivery</b>	on dry ice
<b>Cyrocubes</b>	shape of bottom: cylindrical, conical with round stand-up edges; screw cap with rubber seal; Polypropylen; transparent; to be centrifuged up to 2,000 g; freezable down to -80 °C
<b>Storage Box</b>	white, moisture resistant, crossed compartment inserts, useable for long term storage, freezable down to -80 °C, lid provided

Product number	Trade name	Provided Information
DSPA 4.1.5.2	PCT3	Titer of PCT, ICD10, Disease Score, anamnesis, clinical details, all measured laboratory values, medication, age, gender
DSPA 4.1.5.2.CS	customized specifications* - Sepsis - native PCT (including ICD10)	

\* "customized specifications" are specifications exclusively derived by customers projects. Please send specifications for an individualized offer.

**Panels of recombinant PCT – small volumes**

<b>Intended Use</b>	The <b>in.vent Panels of recombinant PCT – small volumes</b> are designed for the use in R&D and Quality Control departments, mainly for study schemes regarding cut offs, studies for certification.
<b>Matrix</b>	PCT negative true serum off the clot spiked with recombinant PCT
<b>Volume per Sample</b>	0.5 ml
<b>Number of Samples per Sales Unit</b>	20
<b>Number of Samples per Level</b>	5
<b>Number of Levels</b>	4
<b>Constitution of Sample</b>	lyophilized
<b>Instruction for Thawing</b>	add 0.5 ml deionised water, stirr gently
<b>Storage</b>	room temperature (+15 °C to +25 °C)
<b>Delivered Information on Certificate</b>	product number, sample number, matrix, measured laboratory markers, assay system, minimum shelf life, scheme of processing, further information see provided information
<b>Delivery</b>	ambient temperatures
<b>Glass Tubes</b>	screw top vials, 5 ml, 40 x 17.4/1.2 GL14, Fiolax transparent
<b>PCT Levels</b>	< 0.5 ng/ml - 2.0 ng/ml - 5.0 ng/ml - 10 ng/ml

Product number	Trade name
DSPA 4.1.5.3.1	PCT RS
DSPA 4.1.5.3.1.CS	customized specifications* - Sepsis - recombinant PCT

\* "customized specifications" are specifications exclusively derived by customers projects. Please send specifications for an individualized offer.



**Panels of recombinant PCT – large volumes**

<b>Intended Use</b>	The <b>in.vent Panel of recombinant PCT – large volumes</b> is designed for the use in R&D, Quality Control and Production departments, mainly for study schemes regarding cut offs, studies for certification and production purposes.
<b>Matrix</b>	PCT negative true serum off the clot spiked with recombinant PCT
<b>Volume per Sample</b>	5 ml
<b>Number of Samples per Sales Unit</b>	12
<b>Number of Samples per Sales Level</b>	3
<b>Sample Presentation</b>	barcoded glass tubes
<b>Constitution of Sample</b>	lyophilized
<b>Instruction for Thawing</b>	add 5 ml deionised water, stirr gently
<b>Storage</b>	room temperature (+15 °C to +25 °C)
<b>Delivered Information on Certificate</b>	product number, sample number, matrix, measured laboratory results, assay system, minimum shelf life, scheme of processing, further information see provided information
<b>Delivery</b>	ambient temperatures
<b>Glass Tubes</b>	screw top vials, 5 ml, 40 x 17.4/1.2 GL14, Fiolax transparent
<b>Storage Box</b>	white, moisture resistant, useable for long term storage, freezable to -80 °C, lid provided
<b>PCT Levels</b>	< 0.5 ng/ml - 2.0 ng/ml - 5.0 ng/ml - 10 ng/ml

Product number	Trade name
DSPA 4.1.5.3.2	PCT RL
DSPA 4.1.5.3.2.CS	customized specifications* - Sepsis - recombinant PCT

\* "customized specifications" are specifications exclusively derived by customers projects. Please send specifications for an individualized offer.

# Disease State Thyroid Diseases

**in.vent** Panels of Thyroid Disease are designed for use in R&D and Quality Control Departments. They are to be used to differentiate normal population/cohorts with normal levels of analytes from patients. They are used to control performances of laboratory routine testing, new test methods or new equipment as well as for testing of sensitivity/specificity and to evaluate cut offs or normal ranges. The panels consist of native materials without additives.

**Panels of Biomarkers for Thyroid Diseases**

<b>Intended Use</b>	The <b>in.vent Panels of Biomarkers for Thyroid Diseases</b> are designed for the use in R&D and Quality Control departments, mainly for study schemes regarding cut offs, studies for certification. The panel consists of 50 samples from 10 different donors. The samples are chosen by indication. They cover the entire levels of laboratory measurement.
<b>Matrix</b>	true native human serum off the clot
<b>Volume per Sample</b>	0.5 ml
<b>Number of Samples per Sales Unit</b>	20
<b>Number of Samples per Level</b>	4
<b>Number of Levels</b>	5
<b>Number of different Donors</b>	4
<b>Constitution of Sample</b>	liquid frozen
<b>Instruction for Thawing</b>	perpendicular stored at 4 to 10 °C, gently mixing every 0.5 h
<b>Sample Presentation</b>	barcoded cryotubes
<b>Product Presentation</b>	samples sorted in storage box
<b>Storage</b>	-22 to -18 °C
<b>Delivered Information on Certificate</b>	product number, sample number, matrix, volume, age, gender, measured laboratory results, assay system, minimum shelf life, scheme of processing
<b>Delivery</b>	on dry ice
<b>Cryotubes</b>	volume: 0.5 ml; diameter: 10.8 mm; length: 46 mm; shape of bottom: cylindrical, conical with round stand-up edges; screw cap with rubber seal; Polypropylen; transparent; to be centrifuged up to 2,000 g; freezable down to -80 °C
<b>Storage Box</b>	white, moisture resistant, crossed compartment inserts, useable for long term storage, freezable down to -80 °C, lid provided
<b>Provided levels</b>	normal, borderline, low, medium, high levels, extraordinary high levels

Product number	Biomarker
DSPA 4.1.6.1	anti Tg ab
DSPA 4.1.6.2	anti TPO ab
DSPA 4.1.6.3	TRAb
DSPA 4.1.6.4	TSH

Product number	Biomarker
DSPA 4.1.6.5	FT3
DSPA 4.1.6.6	FT4
DSPA 4.1.6.CS	customized specifications* - Thyroid Diseases - Biomarkers, positive

\* "customized specifications" are specifications exclusively derived by customers projects. Please send specifications for an individualized offer.

### Panels free of Biomarkers for Thyroid Diseases

<b>Intended Use</b>	The <b>in.vent Panels free of Biomarkers for Thyroid Diseases</b> are designed for the use in R&D and Quality Control departments, mainly for study schemes regarding cut offs, studies for certification. The panel consists of 50 samples from 10 different donors. The samples are chosen by indication. They cover the intire levels of laboratory measurement.
<b>Matrix</b>	true native human serum off the clot
<b>Volume per Sample</b>	0.5 ml
<b>Number of Samples per Sales Unit</b>	20
<b>Number of Samples per Level</b>	4
<b>Number of different Donors</b>	4
<b>Constitution of Sample</b>	liquid frozen
<b>Instruction for Thawing</b>	perpendicular stored at 4 to 10 °C, gently mixing every 0.5 h
<b>Sample Presentation</b>	barcoded cryotubes
<b>Product Presentation</b>	samples sorted in storage box
<b>Storage</b>	-22 to -18 °C
<b>Delivered Information on Certificate</b>	product number, sample number, matrix, volume, age, gender, measured laboratory results, assay system, minimum shelf life, scheme of processing
<b>Delivery</b>	on dry ice
<b>Cryotubes</b>	volume: 0.5 ml; diameter: 10.8 mm; length: 46 mm; shape of bottom: cylindrical, conical with round stand-up edges; screw cap with rubber seal; Polypropylen; transparent; to be centrifuged up to 2,000 g; freezable down to -80 °C
<b>Storage Box</b>	white, moisture resistant, crossed compartment inserts, useable for long term storage, freezable down to -80 °C, lid provided

Product number	Biomarker
DSPA 4.1.6.2.1	Tg ab negative
DSPA 4.1.6.2.2	TPO negativeTg ab negative
DSPA 4.1.6.2.3	TRAb negative
DSPA 4.1.6.2.4	Tg free
DSPA 4.1.6.2.CS	customized specifications* - Thyroid Diseases - Biomarkers, negative/free

\* "customized specifications" are spezifications exclusively derived by customers projects. Please send specifications for an individualized offer.

### Panels of Thyroid Diseases

<b>Intended Use</b>	The <b>in.vent Panels of Thyroid Diseases</b> are designed for the use in R&D and Quality Control departments, mainly for study schemes regarding cut offs, studies for certification. The panel consists of 50 samples from 50 different donors. The samples are chosen by indication.
<b>Matrix</b>	true native human serum off the clot
<b>Volume per Sample</b>	0.5 ml
<b>Number of Samples per Sales Unit</b>	20
<b>Number of different Donors</b>	4
<b>Constitution of Sample</b>	liquid frozen
<b>Instruction for Thawing</b>	perpendicular stored at 4 to 10 °C, gently mixing every 0.5 h
<b>Sample Presentation</b>	barcoded cryotubes
<b>Product Presentation</b>	samples sorted in storage box
<b>Storage</b>	-22 to -18 °C
<b>Delivered Information on Certificate</b>	product number, sample number, matrix, volume, age, gender, indication, measured laboratory results, assay system, minimum shelf life, scheme of processing
<b>Delivery</b>	on dry ice
<b>Cryotubes</b>	volume: 0.5 ml; diameter: 10.8 mm; length: 46 mm; shape of bottom: cylindrical, conical with round stand-up edges; screw cap with rubber seal; Polypropylen; transparent; to be centrifuged up to 2,000 g; freezable down to -80 °C
<b>Storage Box</b>	white, moisture resistant, crossed compartment inserts, useable for long term storage, freezable down to -80 °C, lid provided

Product number	Biomarker
DSPA 4.1.6.3.1	Hashimoto's Thyroiditis
DSPA 4.1.6.3.2	Hyperthyroidism
DSPA 4.1.6.3.3	Hypothyroidism
DSPA 4.1.6.3.4	Struma

Product number	Biomarker
DSPA 4.1.6.3.5	Thyroid Cancer
DSPA 4.1.6.3.6	Thyroid Nodules
DSPA 4.1.6.3.CS	customized specifications* - Thyroid Diseases - Diseases

\* "customized specifications" are spezifications exclusively derived by customers projects. Please send specifications for an individualized offer.

# Normals Plasma

# 4

**in.vent** Panels of Normal Donors are designed to be used to differentiate normal population/cohorts with normal levels of analytes from patients with abnormal levels of biomarkers. The panels are used to control performances of laboratory routine testing, new test methods or new equipment as well as for testing of sensitivity/specificity and to evaluate cut offs or normal ranges.

Normal/Healthy donors are defined to be "normal" according to the "Bekanntmachung der Richtlinien zur Gewinnung von Blut und Blutbestandteilen und zur Anwendung von Blutprodukten (Hämotherapie) gemäß §§ 12 und 18 des Transfusionsgesetzes (TGF)" published on 4th of May 2010 in the "Bundesanzeiger" by the Paul-Ehrlich Institut, Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel. The following criteria have to be fulfilled for donation of blood, not including plasmapheresis:

1. Anamnesis with initial physical examination by a physician

Criterion	Requirement
2. Leucocytes, Erythrocytes, Thrombocytes, mean corpuscular volume (MCV)	normal
3. Hemoglobin or Hematokrit	female: HB > 125 g/l or HKT > 0,38 l/l male: HB > 135 g/l or HKT > 0,40 l/l
4. Age	18 - 68 years, special criteria for exceptions > 68 years
5. Weight	minimum 50 kg
6. Bloodpressure	systolic: 100 - 180 mm Hg diastolic: < 100 mm Hg
7. Pulse	no clinical signs, frequency 50 - 110/min
8. Temperature	no fever
9. Clinical global Impression	no disease
10. Skin at Puncture Site	no lesion

Furthermore there are several criteria for excluding potential donors as there are e.g. (cited as an extract from the act): neurologic diseases, cardiovascular diseases, malignant neoplasm, allergies.

Infected potential donors are excluded as well in case they are infected with HIV1 or HIV2, HBV, HCV, HTLV type I or type II, protozoonosis diseases or syphilis amongst other.

Potential donors who consume drugs or abnormal volumes of alcohol or abuse of therapeutics are excluded as well. High risk groups like men having sex with men, heterosexual people with high frequently changing partners, male or female prostitutes are excluded also. Further details are listed in the document named above.



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

<b>Intended Use</b>	The <b>in.vent Pools of Normal Human CPD Plasma</b> are intended to be used in production departments for production of controls or standards.
<b>Matrix</b>	Normal Human Citrate-Phosphate-Dextrose Plasma
<b>Filtration</b>	the pool is filtered: 0.2 µm, semi-sterile
<b>Volume per Sales Unit</b>	100 ml – 500 ml
<b>Constitution of Sample</b>	liquid frozen
<b>Instruction for Thawing</b>	perpendicular stored at 4 to 10 °C, gently mixing every 0.5 h
<b>Disease State Testing</b>	tested by CE marked testsystems and found negative for HIV I/II antibodies, p24 antigen, HBsAg, HCV antibodies
<b>Sample Presentation</b>	barcoded bottles
<b>Storage</b>	-22 to -18 °C
<b>Delivered Information on Certificate</b>	product number, matrix, volume, minimum shelf life, result of infectious disease testing, scheme of processing
<b>Delivery</b>	on dry ice
<b>Bottle</b>	white, translucent, low density polypropylen (LDPE), freezable down to -80 °C

Product number	Trade name	Content
NDPO 4.2.1.1	CPD Pool	pool of CPD donations, not further specified
NDPO 4.2.1.2	CPD Pool - Gender mix	pool of CPD donations, 50 % female - 50 % male donors
NDPO 4.2.1.3	CPD Pool - Female	pool of CPD donations, 100 % female donors
NDPO 4.2.1.4	CPD Pool - Male	pool of CPD donations, 100 % male donors
NDPO 4.2.1.5	CPD Pool - Low Triglycerides	pool of CPD donations, gender not specified, with low titers of triglycerides
NDPO 4.2.1.CS	customized specifications* - Plasma Pool	

\* "customized specifications" are specifications exclusively derived by customers projects. Please send specifications for an individualized offer.

# 4

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

<b>Intended Use</b>	The <b>in.vent Bulks of Normal Human CPD Plasma</b> are intended to be used in production departments for production of controls or standards.
<b>Matrix</b>	Normal Human Citrate-Phosphate-Dextrose Plasma
<b>Volume per Sample</b>	one single donation, volumes may vary, minimum volume 300 ml
<b>Constitution of Sample</b>	liquid frozen in bottles
<b>Instruction for Thawing</b>	perpendicular stored at 4 to 10 °C, gently mixing every 0.5 h
<b>Disease State Testing</b>	tested by CE marked test systems and found negative for HIV I/ II antibodies, p24 antigen, HBsAg, HCV antibodies
<b>Sample Presentation</b>	barcoded bottles
<b>Storage</b>	-22 to -18 °C
<b>Delivered Information on Certificate</b>	product number, sample number, matrix, volume, minimum shelf life, result of infectious disease testing, scheme of processing
<b>Delivery</b>	on dry ice
<b>Blood Donation Bag</b>	transparent, freezable down to -30 °C

Product number	Trade name	Content
NDBU 4.2.2.1	CPD - Single Donations	CPD donation, not further specified
NDBU 4.2.2.2	CPD - Single Donations - Female	CPD donation, female donor
NDBU 4.2.2.3	CPD - Single Donations - Male	CPD donation, male donor
NDBU 4.2.2.CS	customized specifications* - Single Donations	

\* "customized specifications" are specifications exclusively derived by customers projects. Please send specifications for an individualized offer.

## Normals Serum

**in.vent** Panels of Normal Donors are designed to be used to differentiate normal population/cohorts with normal levels of analytes from patients with abnormal levels of biomarkers. The panels are used to control performances of laboratory routine testing, new test methods or new equipment as well as for testing of sensitivity/specificity and to evaluate cut offs or normal ranges.

## Pools of Normal Human Sera

<b>Intended Use</b>	The <b>in.vent Pools of Normal Human Sera</b> are suitable for the use in preparation of standards and control materials.
<b>Matrix</b>	true native human serum off the clot
<b>Filtration</b>	the pool is filtered: 0.2 µm, semi-sterile
<b>Volume per Sample Unit</b>	500 ml
<b>Constitution of Sample</b>	liquid frozen
<b>Instruction for Thawing</b>	perpendicular stored at 4 to 10 °C, gently mixing every 0.5 h
<b>Disease State Testing</b>	tested by CE marked test systems and found negative for HIV I/II antibodies, p24 antigen, HBs antigen, HCV antibodies
<b>Sample Presentation</b>	barcoded bottles
<b>Storage</b>	-22 to -18 °C
<b>Delivered Information on Certificate</b>	product number, matrix, volume, minimum shelf life, result of infectious disease testing, scheme of processing
<b>Delivery</b>	on dry ice
<b>Bottle</b>	white, translucent, low density polypropylen (LDPE), freezable down to -80 °C

Product number	Trade name	Content
NDPO 4.2.3.1	Serum Pool	pool of donations, not further specified
NDPO 4.2.3.2	Serum Pool - AB	pool of donations, 50 % female - 50 % male donors
NDPO 4.2.3.3	Serum Pool - Female	pool of donations, 100 % female donors
NDPO 4.2.3.4	Serum Pool - Male	pool of donations, 100 % male donors
NDPO 4.2.3.CS	customized specifications* - Serum Pool	

\* "customized specifications" are specifications exclusively derived by customers projects. Please send specifications for an individualized offer.



## Pools of Normal Human Sera – Cell Culture Quality

<b>Intended Use</b>	The <b>in.vent Pools of Normal Human Sera – Cell Culture Quality</b> are intended to be used in production departments for standards or controls and for cell culture techniques.
<b>Matrix</b>	true native human serum off the clot
<b>Filtration</b>	the pool is filtered: 0.2 µm, semi-sterile
<b>Volume per Sample Unit</b>	500 ml
<b>Constitution of Sample</b>	liquid frozen
<b>Instruction for Thawing</b>	perpendicular stored at 4 to 10 °C, gently mixing every 0.5 h
<b>Disease State Testing</b>	tested by CE marked test systems and found negative for HIV I/II antibodies, p24 antigen, HBs antigen, HCV antibodies
<b>Sample Presentation</b>	barcoded bottles
<b>Storage</b>	-22 to -18 °C
<b>Delivered Information on Certificate</b>	product number, matrix, volume, minimum shelf life, result of infectious disease testing, laboratory results for special specification result of scheme of processing
<b>Bottle</b>	white, translucent, low density polypropylen (LDPE), freezable down to -80 °C
<b>Further Specifications</b>	
sterility	< 10 colony forming units
mycoplasma	not detectable
total protein	5.0 - 8.0 g/dl
hemoglobin	< 15 mg/dl
pH	7.0 - 8.0
osmolality	260 - 320 mOsmol/kg
endotoxin	see certificate of delivery

Product number	Trade name	Content
NDPO 4.3.4.1	Serum Pool	pool of donations, not further specified
NDPO 4.3.4.2	Serum Pool - AB	pool of donations, 50 % female - 50 % male donors
NDPO 4.3.4.3	Serum Pool - Female	pool of donations, 100 % female donors
NDPO 4.3.4.4	Serum Pool - Male	pool of donations, 100 % male donors
NDPO 4.3.4.CS	customized specifications* - Cell Culture	

\* "customized specifications" are specifications exclusively derived by customers projects. Please send specifications for an individualized offer.

# Normals Preanalytics

The **in.vent** Panels of Preanalytics cover a broad range of different stressed samples. The panels are designed to be used in R&D and Quality Control departments, mainly for study schemes regarding the influences of different anticoagulants, temperatures or non-compliant handling of patient samples on the results of the laboratory testing or on biomarkers. All samples of each panel are drawn under identical conditions and donated from the identical donor during one single donation.

### Description of available matrices

<b>True Serum off the Clot</b>	It is obtained by tubes that contain silicate coated on granulate as clot activator. After complete clotting, which is finished between 20 to 30 minutes, the sample is centrifuged. The silicate forms a separating layer between plasma and serum and the serum can be transferred into a separate tube.
<b>True Serum off the Clot obtained by Serum-Gel activator</b>	Additionally to the granulate a special gel (polyacrylate) is added to the tube. This gel forms into a stable layer between the plasma and the corpuscular parts of the blood during centrifugation. Therefore most of the biomarkers stay unharmed during transportation. The serum can be transferred into a separated tube very easily.
<b>K3EDTA</b>	K3EDTA is added to the tube to obtain plasma. K3EDTA samples are used for hematology assays and blood cell count in laboratory routine e.g., because corpuscular parts of the blood stay mostly unharmed. Nevertheless K3EDTA may have some effects on red blood cells: they tend to shrink.
<b>K2EDTA</b>	K2EDTA is recommended as a standard for anticoagulation in hematology of the ICSH (International Council Society of Haematology)
<b>Sodium Citrate</b>	Sodium Citrate is used to obtain plasma. An example for routine use of sodium citrate samples are coagulations assays like PTT or Quick test.
<b>Lithium Heparin</b>	Lithium Heparin coated on granulate or added spray-dried is used as anticoagulants to obtain plasma. In laboratory routine lithium heparine samples are used for blood gas analytics or other assays in clinical chemistry.
<b>Ammonium Heparin (NH4 Heparin)</b>	Ammonium heparine plasma is known as anticoagulants in routine laboratories in end-to-end capillaries e.g.
<b>Sodium Heparin</b>	Sodium Heparin, added spray-dried, is used as anticoagulants to obtain plasma. In laboratory routine use sodium heparin samples are used for blood gas analytics or other assays in clinical chemistry, but lithium heparin samples are preferred.

## Panels of Anticoagulants

<b>Intended Use</b>	The <b>in.vent Panels of Anticoagulants</b> cover a broad range of different anticoagulants which are used in daily routine all over the world. The panels are designed to be used in R&D and Quality Control departments, mainly for study schemes regarding the influences of different anticoagulants on the results of the laboratory testing or on biomarkers. All samples of each panel are drawn under identical conditions and donated from the identical donor during one single donation.
<b>Volume per Sample</b>	0.5 ml
<b>Constitution of Sample</b>	liquid frozen
<b>Instruction for Thawing</b>	perpendicular stored at 4 to 10 °C, gently mixing every 0.5 h
<b>Sample Presentation</b>	barcoded bottles
<b>Storage</b>	ambient temperatures
<b>Delivered Information on Certificate</b>	product number, sample number, matrix, volume, age, gender, minimum shelf life, scheme of processing
<b>Delivery</b>	on dry ice
<b>Cryotubes</b>	volume: 0.5 ml; diameter: 10.8 mm; length: 46 mm; shape of bottom: cylindrical, conical with round stand-up edges; screw cap with rubber seal; Polypropylen; transparent; to be centrifuged up to 2,000 g; freezable down to -80 °C
<b>Storage Box</b>	white, moisture resistant, crossed compartment inserts, useable for long term storage, freezable down to -80 °C, lid provided

Product number	Trade name	Matrices
PAPA 4.4.1.1	Quartet A	4 vials: true human serum off the clot, K3EDTA, sodium citrate, lithium heparin
PAPA 4.4.1.2	Quartet B	4 vials: true human off the clot serum, K3EDTA, sodium citrate, sodium heparin
PAPA 4.4.1.3	Quintet	5 vials: true serum off the clot, serum-gel activator, K3EDTA, sodium citrate, sodium heparin
PAPA 4.4.1.4	Septet	7 vials: true human off the clot, serum-gel activator, K3EDTA, sodium citrate, sodium heparin, lithium heparin, ammonium heparin
PAPA 4.4.1.5	Panel- Lithium Heparin	10 vials of different normal donors, matrix Li- Heparine
PAPA 4.4.1.6	Panel - K2 EDTA	10 vials of different normal donors, matrix K2EDTA
PAPA 4.4.1.7	Panel - K3 EDTA	10 vials of different normal donors, matrix K3EDTA
PAPA 4.4.1.CS	customized specifications* - Anticoagulants	

\* "customized specifications" are specifications exclusively derived by customers projects. Please send specifications for an individualized offer.

## Panels of Freezing and Thawing

<b>Intended Use</b>	The <b>in.vent Panels of Freezing and Thawing</b> are intended for the use in R&D and Quality Control departments, mainly for study schemes regarding the influences of pre-analytical conditions. All samples of each panel are drawn under identical conditions and donated from the identical donor. It simulates the handling of samples which are frozen and thawed several times.
<b>Matrix</b>	true native human serum off the clot from normal donors
<b>Volume per Sample</b>	0.5 ml
<b>Number of Samples</b>	100
<b>Constitution of Sample</b>	liquid frozen
<b>Instruction for Thawing</b>	perpendicular stored at 4 to 10 °C, gently mixing every 0.5 h
<b>Disease State Testing</b>	tested by CE marked testsystems and found negative for HIV I/ II antibodies, p24-antigen, HBsAg, HCV antibodies
<b>Sample Presentation</b>	barcoded cryotubes
<b>Product Presentation</b>	samples sorted in storage box
<b>Storage</b>	-22 to -18 °C
<b>Delivered Information on Certificate</b>	product number, sample number, age, gender, scheme of processing
<b>Cryotubes</b>	volume: 0.5 ml; diameter: 10.8 mm; length: 46 mm; shape of bottom: cylindrical, conical with round stand-up edges; screw cap with rubber seal; Polypropylen; transparent; to be centrifuged up to 2,000 g; freezable down to -80 °C
<b>Storage Box</b>	white, moisture resistant, crossed compartment inserts, useable for long term storage, freezable down to -80 °C, 142 mm x 142 mm x 100 mm, lid provided
<b>Gender Split</b>	50 % female, 50 % male
<b>Details of Processing</b>	
Thawing	at room temperature
Freezing	at -18 °C

Product number	Trade name	Content
PAPA 4.4.2.1	Variations - Freezing/Thawing	1-20 no thawing 21-40 thawed and re-frozen once 41-60 thawed and re-frozen 5 times 61-80 thawed and re-frozen 30 times 81-100 thawed and re-frozen 200 times
PAPA 4.4.2.2	Variations - Storage	1-20: 20 °C 21-40: room temperature 41-60: 10 °C 61-80: -20 °C 81-100: -80 °C
PAPA 4.4.2.CS	customized specifications* - Processing	

\* "customized specifications" are specifications exclusively derived by customers projects. Please send specifications for an individualized offer.



# 4

## Panels of Interfering Substances

<b>Intended Use</b>	The <b>in.vent Panels of Interfering Substances</b> cover a broad range of interfering substances that occur in daily routine lab testing. They are designed to be used in R&D and Quality Control departments, mainly for study schemes regarding the influences of pre-analytical conditions to prevent the false positive or negative results in routine labs. They are used as well in studies for certification. The samples are not sorted by age or gender.
<b>Matrix</b>	true native human serum off the clot resp. plasma (additive as described)
<b>Volume per Sample</b>	0.5 ml
<b>Number of Samples</b>	50
<b>Number of Interfering Substances</b>	9
<b>Included Interfering Substances</b>	Haemolysis, Bilirubin, Lipids, HAMA, heterophile antibodies, E.coli Ab, several proteins, rheumatoid factor, pregnancy
<b>Constitution of Sample</b>	liquid frozen
<b>Instruction for Thawing</b>	perpendicular stored at 4 to 10 °C, gently mixing every 0.5 h
<b>Sample Presentation</b>	barcoded cryotubes
<b>Storage</b>	-22 to -18 °C
<b>Delivered Information on Certificate</b>	age, gender, scheme of processing
<b>Cryotubes</b>	volume: 0.5 ml; diameter: 10.8 mm; length: 46 mm; shape of bottom: cylindrical, conical with round stand-up edges; screw cap with rubber seal; Polypropylen; transparent; to be centrifuged up to 2,000 g; freezable down to -80 °C
<b>Storage Box</b>	white, moisture resistant, crossed compartment inserts, useable for long term storage, freezable down to -80 °C, 142 mm x 142 mm x 100 mm, lid provided

Product number	Trade name
IFPA 4.5.1.1	Interfering Panel
IFPA 4.5.1.CS	customized specifications* - Interfering Substances

\* "customized specifications" are specifications exclusively derived by customers projects. Please send specifications for an individualized offer.

# Normals Ultrastatistics

**in.vent** Panels and Pools of Ultrastatistics are designed to be used to differentiate normal population/cohorts with normal levels of analytes from patients with abnormal levels of biomarkers. The panels and pools are used to control performances of laboratory routine testing, new test methods or new equipment as well as for testing of sensitivity/specificity and to evaluate cut offs or normal ranges.

## Ultrastatistic Panels

<b>Intended Use</b>	The <b>in.vent Ultrastatistic Panels</b> are representative panels for groups of ages and gender. They are intended to be used e.g. in R&D and Quality Control Departments, mainly for study schemes regarding normal ranges of titers of biomarkers.
<b>Matrix</b>	true native human serum off the clot
<b>Volume per Vial</b>	0.5 ml
<b>Number of Samples per Sales Unit</b>	see Content
<b>Constitution of Sample</b>	liquid frozen
<b>Instruction for Thawing</b>	perpendicular stored at 4 to 10 °C, gently mixing every 0.5 h
<b>Disease State Testing</b>	tested by CE marked testsystems and found negative for HIV I/II antibodies, p24 antigen, HBsAg, HCV antibodies
<b>Sample Presentation</b>	barcoded cryotubes
<b>Product Presentation</b>	samples sorted in storage box
<b>Storage</b>	-22 to -18 °C
<b>Delivered Information on Certificate</b>	productnumber, matrix, volume, age, gender, measured laboratory results, assay system, minimum shelf life, result of infectious disease testing, scheme of processing
<b>Delivery</b>	ambient temperatures
<b>Cryotubes</b>	volume: 0.5 ml; diameter: 10.8 mm; length: 46 mm; shape of bottom: cylindrical, conical with round stand-up edges; screw cap with rubber seal; Polypropylen; transparent; to be centrifuged up to 2,000 g; freezable down to -80 °C
<b>Storage Box</b>	white, moisture resistant, crossed compartment inserts, useable for long term storage, freezable down to -80 °C, lid provided
<b>Groups of ages</b>	18 - 65 years, not sorted
<b>Gender Split</b>	female, male, not sorted

Product number	Trade name	Content
USPA 4.6.1	Ultrastatistic Panel 100	100 different European normal donors
USPA 4.6.2	Ultrastatistic Panel 1,000	1,000 different European normal donors
USPA 4.6.2.CS	customized specifications* - Ultrastatistic Panel	

\* "customized specifications" are specifications exclusively derived by customers projects. Please send specifications for an individualized offer.

## Ultrastatistic Panels – sorted by age and gender

<b>Intended Use</b>	The <b>in.vent Ultrastatistic Panels</b> sorted by age and gender are representative panels for groups of ages and gender and sorted by groups of ages as well as by gender. They are intended to be used e.g. in R&D and Quality Control Departments, mainly for study schemes regarding normal ranges of titers of biomarkers.
<b>Matrix</b>	true native human serum off the clot
<b>Volume per Vial</b>	0.5 ml
<b>Number of Samples per Sales Unit</b>	100 samples divided into 20 samples per group of ages
<b>Constitution of Sample</b>	liquid frozen
<b>Instruction for Thawing</b>	perpendicular stored at 4 to 10 °C, gently mixing every 0.5 h
<b>Disease State Testing</b>	tested by CE marked testsystems and found negative for HIV I/II antibodies, p24 antigen, HBsAg, HCV antibodies
<b>Sample Presentation</b>	barcoded cryotubes
<b>Product Presentation</b>	samples sorted in storage box
<b>Storage</b>	-22 to -18 °C
<b>Delivered Information on Certificate</b>	product number, sample number, matrix, volume, age, gender, minimum shelf life, result of infectious disease testing, scheme of processing
<b>Delivery</b>	on dry ice
<b>Cryotubes</b>	volume: 0.5 ml; diameter: 10.8 mm; length: 46 mm; shape of bottom: cylindrical, conical with round stand-up edges; screw cap with rubber seal; Polypropylen; transparent; to be centrifuged up to 2,000 g; freezable down to -80 °C
<b>Storage Box</b>	white, moisture resistant, crossed compartment inserts, useable for long term storage, freezable at -80 °C, 142 mm x 142 mm x 100 mm, lid provided
<b>Groups of Ages</b>	18 - 25 26 - 35 36 - 45 46 - 55 56 - 65
<b>Gender Split</b>	50 % female, 50 % male

Product number	Trade name	Content
USPA 4.6.3	Ultrastatistic Panel 100 (age, gender)	100 normal european donors
USPA 4.6.4	Ultrastatistic Panel 1,000 (age, gender)	1,000 normal european donors
USPA 4.6.CS	customized specifications* - Ultrastatistic Panel (age, gender)	

\* "customized specifications" are specifications exclusively derived by customers projects. Please send specifications for an individualized offer.

## Ultrastatistic Pools 5,000

<b>Intended Use</b>	The <b>in.vent Ultrastatistic Pool 5,000</b> is a pool which is representative for the average European population. It is a pool of 5,000 normal European Donors. It is designed to be used e.g. in academic research, R&D, Quality Control departments mainly for study schemes regarding normal ranges of titers of biomarkers as well as for production of controls or standards.		
<b>Matrix</b>	true native human serum off the clot		
<b>Filtration</b>	the pool is filtered: 0.2 µm, semi-sterile		
<b>3 possible Volumes per Sample</b>	0.5 ml	10 ml	100 ml
<b>Number of Samples per Sales Unit</b>	0.5 ml 10	10 ml 1	100 ml 1
<b>Number of Samples in the Pool</b>	5,000		
<b>Product presentation 0.5 ml</b>	liquid frozen in barcoded cryotubes		
<b>Product presentation 10 ml, 100 ml</b>	liquid frozen in barcoded bottles		
<b>Instruction for Thawing</b>	perpendicular stored at 4 to 10 °C, gently mixing every 0.5 h		
<b>Disease State Testing</b>	tested by CE marked testsystems and found negative for HIV I/II antibodies, p24 antigen, HBsAg, HCV antibodies		
<b>Storage</b>	-22 to -18 °C		
<b>Delivered Information on Certificate</b>	product number, matrix, volume, minimum shelf life, result of infectious disease testing, scheme of processing		
<b>Delivery</b>	on dry ice		
<b>Cryotubes</b>	volume: 0.5 ml; diameter: 10.8 mm; length: 46 mm; shape of bottom: cylindrical, conical with round stand-up edges; screw cap with rubber seal; Polypropylen; transparent; to be centrifuged up to 2,000 g; freezable down to -80 °C		
<b>Bottles</b>	10 ml	100 ml	
maximum diameter	26.00 mm	47.0 mm	
height	46.5 mm	105.0 mm	
material	polyethylen low density (LDPE)	polyethylen low density (LDPE)	
colour	white, translucentwhite, translucent		
<b>Storage Box for Cryotubes</b>	white, moisture resistant, crossed compartment inserts, useable for long term storage, freezable down to -80 °C, lid provided		

Product number	Trade name	Content
USPO 4.6.6	Ultrastatistic Pool 5,000	5,000 different donations in equal share of male and female normal donors
USPO 4.6.6.CS	customized specifications* - Ultrastatistic Pool	

\* "customized specifications" are specifications exclusively derived by customers projects. Please send specifications for an individualized offer.

# Fertility & Pregnancy Normals

# 4

**in.vent** Panels of Pregnancy and Fertility are designed for use in R&D Departments. They are to be used to differentiate normal population/cohorts with normal levels of analytes from patients. They are used to control performances of laboratory routine testing, new test methods or new equipment as well as for testing of sensitivity/specificity and to evaluate cut offs or normal ranges.

## Panels of Normal Pregnancy – single donations

<b>Intended Use and Content</b>	The <b>in.vent Panels of Normal Pregnancy – single donations</b> is designed for the use in R&D and Quality Control departments, mainly for study schemes regarding cut offs, studies for certification. The panel consists of 90 samples from 90 different donors, not sorted by age. 30 samples from different donors per trimester are provided. Donors are self reported healthy.
<b>Matrix</b>	true native human serum off the clot
<b>Volume per Sample</b>	0.5 ml
<b>Number of Donors</b>	90
<b>Number of Samples per Trimester</b>	30
<b>Constitution of Sample</b>	liquid frozen
<b>Instruction for Thawing</b>	perpendicular stored at 4 to 10 °C, gently mixing every 0.5 h
<b>Disease State Testing</b>	tested by CE marked testsystems and found negative for HIV I/II antibodies, p24 antigen, HBsAg, HCV antibodies
<b>Product Presentation</b>	barcoded cryotubes
<b>Storage</b>	-22 to -18 °C
<b>Delivered Information on Certificate</b>	product number, sample number, matrix, volume, age, gender, week of pregnancy, minimum shelf life, scheme of processing
<b>Delivery</b>	on dry ice
<b>Cryotubes</b>	volume: 0.5 ml; diameter: 10.8 mm; length: 46 mm; shape of bottom: cylindrical, conical with round stand-up edges; screw cap with rubber seal; Polypropylen; transparent; to be centrifuged up to 2,000 g; freezable down to -80 °C
<b>Storage Box</b>	white, moisture resistant, crossed compartment inserts, useable for long term storage, freezable down to -80 °C, lid provided

Product number	Trade name
FPPA 4.7.1	Pregnancy Mix
FPPA 4.7.1.CS	customized specifications* - Pregnancy

\* "customized specifications" are specifications exclusively derived by customers projects. Please send specifications for an individualized offer.

## Panels of Normal Pregnancy – consecutive donations

<b>Intended Use</b>	The <b>in.vent Panels of Normal Pregnancy – consecutive donations</b> are designed for the use in R&D and Quality Control departments, mainly for study schemes regarding cut offs, studies for certification. The panel consists of 60 samples from 20 different donors, not sorted by age. 1 sample per donor per trimester is provided.
<b>Matrix</b>	true native human serum off the clot
<b>Volume per Sample</b>	0.5 ml
<b>Number of Samples</b>	60
<b>Number of Donors</b>	20
<b>Constitution of Sample</b>	liquid frozen
<b>Instruction for Thawing</b>	perpendicular stored at 4 to 10 °C, gently mixing every 0.5 h
<b>Sample Presentation</b>	barcoded cryotubes
<b>Storage</b>	-22 to -18 °C
<b>Delivered Information on Certificate</b>	product number, sample number, matrix, volume, age, gender, week of pregnancy, minimum shelf life, scheme of processing
<b>Delivery</b>	on dry ice
<b>Cryotubes</b>	volume: 0.5 ml; diameter: 10.8 mm; length: 46 mm; shape of bottom: cylindrical, conical with round stand-up edges; screw cap with rubber seal; Polypropylen; transparent; to be centrifuged up to 2,000 g; freezable down to -80 °C
<b>Storage Box</b>	white, moisture resistant, crossed compartment inserts, useable for long term storage, freezable down to -80 °C, lid provided

Product number	Trade name
FPPA 4.7.2	Panel of Normal Pregnancy CD
FPPA 4.7.2.CS	customized specifications* - consecutive donations

\* "customized specifications" are specifications exclusively derived by customers projects. Please send specifications for an individualized offer.



# Fertility & Pregnancy Disease State

**in.vent** Panels of Pregnancy and Fertility – Disease State are designed for use in R&D and Quality Control Departments. They are used to control performances of laboratory routine testing, new test methods or new equipment as well as for testing of sensitivity/specificity and to evaluate cut offs or normal ranges.

## Panels of Pregnancy – associated diseases

<b>Intended Use and Content</b>	The <b>in.vent Panels of Pregnancy – associated diseases</b> are designed for the use in R&D and Quality Control departments, mainly for study schemes regarding cut offs, studies for certification. The panel consists of 60 samples from 60 different donors. Information is given regarding age, week of pregnancy, previous pregnancies, abortions or fetal loss. Samples are chosen by indication, not sorted.
<b>Matrix</b>	true native human serum off the clot
<b>Volume per Sales Unit</b>	0.5 ml
<b>Number of Donors</b>	60
<b>Number of Samples</b>	60
<b>Constitution of Sample</b>	liquid frozen
<b>Instruction for Thawing</b>	perpendicular stored at 4 to 10 °C, gently mixing every 0.5 h
<b>Product Presentation</b>	barcoded cryotubes
<b>Storage</b>	-22 to -18 °C
<b>Delivered Information on Certificate</b>	product number, sample number, matrix, volume, age, gender, week of pregnancy, indication, previous pregnancies, abortions or fetal loss, minimum shelf life, scheme of processing
<b>Delivery Cryotubes</b>	on dry ice volume: 0.5 ml; diameter: 10.8 mm; length: 46 mm; shape of bottom: cylindrical, conical with round stand-up edges; screw cap with rubber seal; Polypropylen; transparent; to be centrifuged up to 2,000 g; freezable down to -80 °C
<b>Storage Box</b>	white, moisture resistant, crossed compartment inserts, useable for long term storage, freezable down to -80 °C, lid provided

Product number	Trade name
FPPA 4.7.8	Pregnancy AD
FPPA 4.7.8.CS	customized specifications* - disease associated with pregnancy

\* "customized specifications" are specifications exclusively derived by customers projects. Please send specifications for an individualized offer.

## Panels of Cord Blood

<b>Intended Use</b>	The <b>in.vent Panels of Cord Blood</b> are designed for the use in R&D and Quality Control departments, mainly for study schemes regarding cut offs, studies for certification. The panel consists of 10 samples from 10 different donors. Information is given regarding age, week of pregnancy, previous pregnancies, abortions or fetal loss. Donors are self reported healthy.
<b>Matrix</b>	Cord Blood resp. Cord Blood + corresponding serum
<b>Volume per Sample</b>	0.5 ml
<b>Number of Samples per Sales Unit</b>	10
<b>Number of Donors</b>	10
<b>Constitution of Sample</b>	liquid frozen
<b>Instruction for Thawing</b>	perpendicular stored at 4 to 10 °C, gently mixing every 0.5 h
<b>Storage</b>	-22 to -18 °C
<b>Delivered Information on Certificate</b>	product number, sample number, matrix, volume, age, gender of child, week of pregnancy, indication, previous pregnancies, abortions or fetal loss, minimum shelf life, scheme of processing
<b>Delivery Cryotubes</b>	on dry ice volume: 0.5 ml; diameter: 10.8 mm; length: 46 mm; shape of bottom: cylindrical, conical with round stand-up edges; screw cap with rubber seal; Polypropylen; transparent; to be centrifuged up to 2,000 g; freezable down to -80 °C
<b>Storage Box</b>	white, moisture resistant, crossed compartment inserts, useable for long term storage, freezable down to -80 °C, lid provided

Product number	Trade name
FPPA 4.7.3	Cord Blood
FPPA 4.7.4	Cord Blood & corresponding serum
FPPA 4.7.4.CS	customized specifications* - Cord Blood

\* "customized specifications" are specifications exclusively derived by customers projects. Please send specifications for an individualized offer.

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## Summary of products 2015/2016

Product number	Trade name
<b>Diagnostic Clinical Trials</b>	
1.1 CS	
<b>Quality Control</b>	
<b>in.QualiCheck®</b>	
QC 2.1.1	Thyroid autoimmune diseases
QC 2.1.2	Systemic Inflammation
QC 2.1.3	Diabetes mellitus Type I
QC 2.1.4	Rheumatoid Arthritis
QC 2.1.5	Celiac Disease
<b>in.QualiCheck®</b>	
QC 2.2.1	Autoimmunity
QC 2.2.2	Cardiac Marker
QC 2.2.3	Clinical Chemistry
QC 2.2.4	Hormones
QC 2.2.5	Infectious Diseases
QC 2.2.6	Oncology
QC 2.2.7	Pregnancy/Fertility
QC 2.2.8	Therapeutics
QC 2.2.9	Urine
QC 2.2.CS	customized specifications* - Proficiency Testing Quality
<b>Proteinchemistry</b>	
<b>Antibodies</b>	
PC 3.1.1	MIS3
PC 3.1.2	MIS5
<b>Proteins</b>	
PC 3.2.1	MIS TSH-R
PC 3.2.2	hnRNP B1
<b>Human Biomaterials</b>	
<b>Disease State - Autoimmunity - Biomarkers</b>	
DSPA 4.1.1.1.1	anti dsDNA
DSPA 4.1.1.1.2	anti Centromere
DSPA 4.1.1.1.3	anti Gliadin IgA
DSPA 4.1.1.1.4	anti Gliadin IgG
DSPA 4.1.1.1.5	anti La
DSPA 4.1.1.1.6	anti SCL70
DSPA 4.1.1.1.7	anti tTg IgA
DSPA 4.1.1.1.8	anti tTg IgG
DSPA 4.1.1.1.9	customized specifications* - Panels of Autoimmune Biomarkers

Product number	Trade name
<b>Disease State - Autoimmunity - Indications (including ICD10)</b>	
DSPA 4.1.1.2.1	Coeliac Disease
DSPA 4.1.1.2.2	Dermatomyositis - Polymyositis
DSPA 4.1.1.2.3	Fibromyalgia
DSPA 4.1.1.2.4	Graves' Disease*
DSPA 4.1.1.2.5	Hashimoto's Disease*
DSPA 4.1.1.2.6	MCTD
DSPA 4.1.1.2.7	Myositis
DSPA 4.1.1.2.8	PSS
DSPA 4.1.1.2.9	Reactive Arthritis
DSPA 4.1.1.2.10	Rheumatoid Arthritis
DSPA 4.1.1.2.11	SAPHO-Syndrome
DSPA 4.1.1.2.12	Sjogren's Syndrome
DSPA 4.1.1.2.13	Spondylitis ankylosans
DSPA 4.1.1.2.14	Wegener's Granulomatosis
DSPA 4.1.1.2.CS	customized specifications* - Panels of autoimmune Indications (including ICD10)
<b>Disease State - Autoimmunity - Indications (without ICD10)</b>	
DSPA 4.1.1.3.1	Coeliac Disease
DSPA 4.1.1.3.2	Rheumatoid Arthritis A
DSPA 4.1.1.3.3	Rheumatoid Arthritis B
DSPA 4.1.1.3.4	Graves' Disease*
DSPA 4.1.1.3.5	Hashimoto's Disease*
DSPA 4.1.1.3.CS	customized specifications* - Panels of autoimmune Indications
*further Thyroid Diseases see Chapter Thyroid Diseases	
<b>Disease State - Drugs of Abuse - CDT</b>	
DSPA 4.1.2.1.1	CDT Panel
DSPA 4.1.2.1.1.CS	customized specifications* - Drugs of Abuse - Panel
DSPA 4.1.2.1.2	CDT Pool
DSPA 4.1.2.1.2.CS	customized specifications* - Drugs of Abuse - Pool
DSPA 4.1.2.1.3	CDT Urine & Serum
DSPA 4.1.2.1.3.CS	customized specifications* - Drugs of Abuse - Urine & Serum
<b>Disease State - Diabetes - Biomarkers</b>	
DSPA 4.1.3.1.1	Insulin ab (IAA)
DSPA 4.1.3.1.2	Icelet cell ab (ICA)
DSPA 4.1.3.1.3	Tyrosine - Phospatase ab (IA2)

Product number	Trade name
DSPA 4.1.3.1.4	Glutamate - Decarboxylase ab (GADA)
DSPA 4.1.3.1.5	customized specifications* - Panels of Diabetes I
DSPA 4.1.3.1.6	HbA1c EDTA whole blood
DSPA 4.1.3.1.7	HbA1c Serum
DSPA 4.1.3.1.8	Glucosis Urine
DSPA 4.1.3.1.CS	customized specifications* - Panels of Diabetes II
<b>Disease State - Diabetes - Indications</b>	
DSPA 4.1.3.2.1	Panel Diabetes Type I
DSPA 4.1.3.2.2	Panel Diabetes Type II
DSPA 4.1.3.2.3	Panel selected medication
DSPA 4.1.3.2.CS1	customized specifications* - Indications - Diabetes I
DSPA 4.1.3.2.CS2	customized specifications* - Indications - Diabetes II
<b>Disease State - Infectiology - Serum</b>	
DSPA 4.1.4.1.1	Cytomegalovirus IgG (CMV IgG)
DSPA 4.1.4.1.2	Cytomegalovirus IgM (CMV IgM)
DSPA 4.1.4.1.3	Chlamydia pneumoniae IgA
DSPA 4.1.4.1.4	Chlamydia pneumoniae IgG
DSPA 4.1.4.1.5	Chlamydia pneumoniae IgM
DSPA 4.1.4.1.6	Chlamydia trachomatis IgA
DSPA 4.1.4.1.7	Chlamydia trachomatis IgG
DSPA 4.1.4.1.8	Chlamydia trachomatis IgM
DSPA 4.1.4.1.9	Epstein Barr Virus IgG (EBV IgG)
DSPA 4.1.4.1.10	Epstein Barr Virus IgM (EBV IgM)
DSPA 4.1.4.1.11	Helicobacter pylori IgG
DSPA 4.1.4.1.12	Helicobacter pylori IgM
DSPA 4.1.4.1.13	Hepatitis B surface antigen (HBsAG)
DSPA 4.1.4.1.14	Hepatitis B core antibody IgM
DSPA 4.1.4.1.15	Hepatitis C IgG (HCV IgG)
DSPA 4.1.4.1.16	Herpes simplex virus 1 IgG (HSV 1 IgG)
DSPA 4.1.4.1.17	Herpes simplex virus 1 IgM (HSV 1 IgM)
DSPA 4.1.4.1.18	Herpes simplex virus 2 IgG (HSV 2 IgG)
DSPA 4.1.4.1.19	Herpes simplex virus 2 IgM (HSV 2 IgM)
DSPA 4.1.4.1.20	Human L Lymphotropic Virus (HTLV)
DSPA 4.1.4.1.21	Malaria

Product number	Trade name
DSPA 4.1.4.1.22	Measles
DSPA 4.1.4.1.23	Mycoplasma pneumoniae
DSPA 4.1.4.1.24	Parvovirus B19
DSPA 4.1.4.1.25	Rubella IgG
DSPA 4.1.4.1.26	Rubella IgM
DSPA 4.1.4.1.27	Syphilis (TPA)
DSPA 4.1.4.1.28	Toxoplasma IgG
DSPA 4.1.4.1.29	Toxoplasma IgM
DSPA 4.1.4.1.CS	customized specifications* - Infectiology - Serum
<b>Disease State - Infectiology - Plasma</b>	
DSPA 4.1.4.2.1	CMV IgG
DSPA 4.1.4.2.2	Helicobacter pylori
DSPA 4.1.4.2.3	HBV
DSPA 4.1.4.2.4	HCV
DSPA 4.1.4.2.5	Rubella IgG
DSPA 4.1.4.2.6	Toxoplasma gondii
DSPA 4.1.4.2.CS	customized specifications* - Infectiology - Plasma
<b>Disease State - Infectiology - Lyme Disease</b>	
DSPA 4.1.4.3	Lyme Disease Panel A
DSPA 4.1.4.3.CS	customized specifications* - Lyme Disease
DSPA 4.1.4.4	Lyme Disease Panel B
DSPA 4.1.4.4.CS	customized specifications* - Lyme Disease (including detailed data)
<b>Disease State - Sepsis - native PCT</b>	
DSPA 4.1.5.1.1	PCT1
DSPA 4.1.5.1.1.CS	customized specifications* - Sepsis - native PCT
DSPA 4.1.5.1.2	PCT2
DSPA 4.1.5.1.2.CS	customized specifications* - Sepsis - native PCT (including detailed data)
<b>Disease State - Sepsis - native PCT (including ICD10)</b>	
DSPA 4.1.5.2	PCT3
DSPA 4.1.5.2.CS	customized specifications* - Sepsis - native PCT (including ICD10)
<b>Disease State - Sepsis - recombinant PCT</b>	
DSPA 4.1.5.3.1	PCT RS
DSPA 4.1.5.3.1.CS	customized specifications* - Sepsis - recombinant PCT
DSPA 4.1.5.3.2	PCT RL
DSPA 4.1.5.3.2.CS	customized specifications* - Sepsis - recombinant PCT

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Product number	Trade name
<b>Disease State - Thyroid Diseases - Biomarkers, positive</b>	
DSPA 4.1.6.1	anti Tg ab
DSPA 4.1.6.2	anti TPO ab
DSPA 4.1.6.3	TRAb
DSPA 4.1.6.4	TSH
DSPA 4.1.6.5	FT3
DSPA 4.1.6.6	FT4
DSPA 4.1.6.CS	customized specifications* - Thyroid Diseases - Biomarkers, positive
<b>Disease State - Thyroid Diseases - Biomarkers, negative/free</b>	
DSPA 4.1.6.2.1	Tg ab negative
DSPA 4.1.6.2.2	TPO negative/Tg ab negative
DSPA 4.1.6.2.3	TRAb negative
DSPA 4.1.6.2.4	Tg free
DSPA 4.1.6.2.CS	customized specifications* - Thyroid Diseases - Bio-markers, negative/free
<b>Disease State - Thyroid Diseases - Indications</b>	
DSPA 4.1.6.3.1	Hashimoto's Thyroiditis
DSPA 4.1.6.3.2	Hyperthyroidism
DSPA 4.1.6.3.3	Hypothyroidism
DSPA 4.1.6.3.4	Struma
DSPA 4.1.6.3.5	Thyroid Cancer
DSPA 4.1.6.3.6	Thyroid Nodules
DSPA 4.1.6.3.CS	customized specifications* - Thyroid Diseases - Diseases
<b>Normal Plasma - Pools</b>	
NDPO 4.2.1.1	CPD Pool
NDPO 4.2.1.2	CPD Pool - Gender mix
NDPO 4.2.1.3	CPD Pool - Female
NDPO 4.2.1.4	CPD Pool - Male
NDPO 4.2.1.5	CPD Pool - Low Triglycerides
NDPO 4.2.1.CS	customized specifications* - Plasma Pool
<b>Normal Plasma - Bulks</b>	
NDBU 4.2.2.1	CPD - Single Donations
NDBU 4.2.2.2	CPD - Single Donations - Female
NDBU 4.2.2.3	CPD - Single Donations - Male
NDBU 4.2.2.CS	customized specifications* - Single Donations

Product number	Trade name
<b>Normal Serum - Pools</b>	
NDPO 4.2.3.1	Serum Pool
NDPO 4.2.3.2	Serum Pool - AB
NDPO 4.2.3.3	Serum Pool - Female
NDPO 4.2.3.4	Serum Pool - Male
NDPO 4.2.3.CS	customized specifications* - Serum Pool
<b>Cell Culture Quality - Pools</b>	
NDPO 4.3.4.1	Serum Pool
NDPO 4.3.4.2	Serum Pool - AB
NDPO 4.3.4.3	Serum Pool - Female
NDPO 4.3.4.4	Serum Pool - Male
NDPO 4.3.4.CS	customized specifications* - Cell Culture
<b>Preanalytics - Anticoagulants</b>	
PAPA 4.4.1.1	Quartet A
PAPA 4.4.1.2	Quartet B
PAPA 4.4.1.3	Quintet
PAPA 4.4.1.4	Septet
PAPA 4.4.1.5	Panel - Lithium Heparin
PAPA 4.4.1.6	Panel - K2 EDTA
PAPA 4.4.1.7	Panel - K3 EDTA
PAPA 4.4.1.CS	customized specifications* - Anticoagulants
<b>Preanalytics - Processing</b>	
PAPA 4.4.2.1	Variations - Freezing/ Thawing
PAPA 4.4.2.2	Variations - Storage
PAPA 4.4.2.CS	customized specifications* - Processing
<b>Interfering Substances</b>	
IFPA 4.5.1.1	Interfering Panel
IFPA 4.5.1.CS	customized specifications* - Interfering Substances
<b>Ultrastatistics</b>	
USPA 4.6.1	Ultrastatistic Panel 100
USPA 4.6.2	Ultrastatistic Panel 1,000
USPA 4.6.2.CS	customized specifications* - Ultrastatistic Panel
USPA 4.6.3	Ultrastatistic Panel 100 (age, gender)
USPA 4.6.4	Ultrastatistic Panel 1,000 (age, gender)
USPA 4.6.CS	customized specifications* - Ultrastatistic Panel (age, gender)
USPO 4.6.6	Ultrastatistic Pool 5,000
USPO 4.6.6.CS	customized specifications* - Ultrastatistic Pool

Product number	Trade name
<b>Fertility &amp; Pregnancy</b>	
FPPA 4.7.1	Pregnancy Mix
FPPA 4.7.1.CS	customized specifications* - Pregnancy
FPPA 4.7.2	Panel of Normal Pregnancy CD
FPPA 4.7.2.CS	customized specifications* - consecutive donations
FPPA 4.7.3	Cord Blood
FPPA 4.7.4	Cord Blood & corresponding serum
FPPA 4.7.4.CS	customized specifications* - Cord Blood
FPPA 4.7.8	Pregnancy AD
FPPA 4.7.8.CS	customized specifications* - disease associated with pregnancy

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# Human Biomaterials



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