

*We are human*

**in.vent**  
DIAGNOSTICA GMBH

# Product List

Human Biomaterials  
2023/24



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## We keep you up to date!

www.inventdiagnostica.de

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*We are human*

**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 Biomaterials since 2001.

**in.vent** is focussed on the customised procurement of Human Biomaterials. Further fields of activities are the production of biomarkers of human origin, quality controls, standard materials and clinical studies.

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

**in.vent's** clients profit from the team of high qualified scientists with extensive and deep knowledge of Human Biomaterials 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>1</sup> & Declaration of Taipei<sup>2</sup> as developed by the World Medical Association state the ethical principles that provide guidance to physicians and other participants in medical research involving human subjects research on Health Databases, Big Data and Biobanks are basis of our guidelines.
2. in.vent only cooperates with networks, physicians, clinics and other organisations that comply with these standards.
3. Further standards are based on the requirements of IVDR 2017/746.<sup>3</sup>
4. The notes of the German Central Ethical Committee<sup>4</sup> and the German Ethics Board regarding biobanks for research purposes are taken into consideration as well as far as they are applicable.
5. Furthermore ICH-GCP guidelines<sup>5</sup> (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use – Good Clinical Practice) are taken into account whenever applicable.

- Human Biomaterials are valuable biomaterials for research, development and production of IVDs, companion diagnostics, pharmaceutical and clinical 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 reasons.
- All donations are preceded by statements according the ethical correctness of the projects of an International Review Board (IRB)<sup>6</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 Human Biomaterials are pseudonymised resp. anonymised 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.
- The collection, storage and the use of data is subject of the Declaration of Taipei. Individuals have the right to request and to be provided with information about their data at any time<sup>7</sup>.
- in.vent maintains a Quality Management System certified according to ISO 13485<sup>8</sup> and ISO 9001<sup>9</sup>.
- The compliance with the above mentioned standards is kept under strict surveillance.
- in.vent trains and informs its employees to ensure compliance with these standards on a regularly basis.

1 <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects>

2 <http://www.ak-med-ethik-komm.de/docs/WMA-Declaration-of-Taipei-2016.pdf>

3 <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R0746&from=EN>

4 <https://www.ce-richtlinien.eu/in-vitro-diagnostika>

5 <http://www.ich.org/products/guidelines.html>

6 <http://www.feki.com/index.php?ic=10>

7 <http://www.ak-med-ethik-komm.de/docs/WMA-Declaration-of-Taipei-2016.pdf>

8 <https://www.mdc-ce.de/medizinprodukte/leistungen/qm-zertifizierung/iso-13485.html>

9 <https://www.mdc-ce.de/gesundheitswesen/leistungen/qm-zertifizierung/iso-9001.html>

# Product Overview

## Panels & Controls

We offer samples off-the-shelf, prospective collections and customised samples for developing your assays. Our team provides a wide range of different biomarkers and controls and multiple matrices.

- standard delivery of panels and controls: ambient temperatures or lyophilised or blue ice or dry ice with or without temperature monitoring systems
- standard storage of panels and controls: according to constitution of sample
- instruction for thawing: reconstitution instruction delivered with lyophilised controls

## Bulks

Large volume single donations of normal and disease state donors are part of our portfolio of native human biomaterials. We offer standard and customised bulks used for academic research, studies, development and production for non-therapeutical use.

- standard delivery of bulks: on dry ice
- standard storage of bulks: -18°C
- constitution of samples: liquid frozen
- instruction for thawing: perpendicular stored at 4 to 10°C, gently mixing every 0.5h

## Pools

The samples were gained, processed and verified in a way that is ethically and legally compliant for the purposes of diagnostic research and development, production and quality assurance for non-therapeutical use.

- standard delivery of pools: on dry ice
- standard storage of pools: -18°C
- constitution of samples: liquid frozen
- instruction for thawing: perpendicular stored at 4 to 10°C, gently mixing every 0.5h

## Collectives

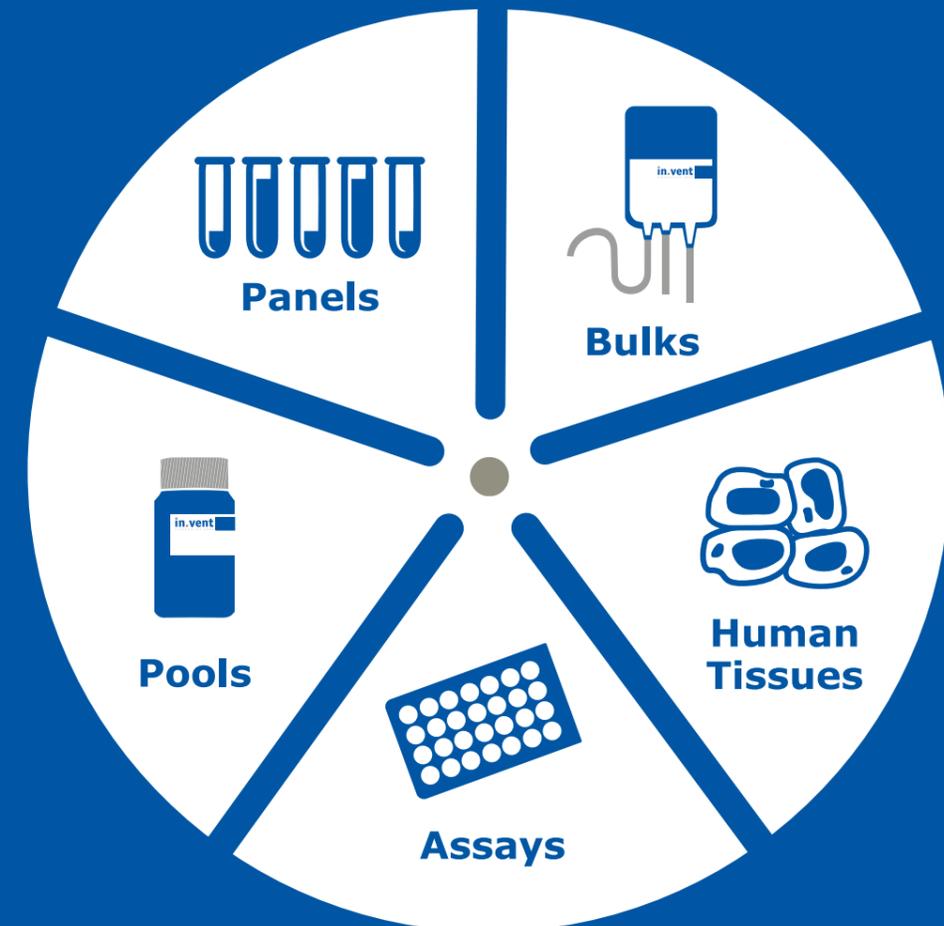
We compile collectives for you that cover different clinical pictures (e.g. collagenoses and thyroid diseases).

## Human Tissues

Human Tissues are a high potential Resource for Extraction of many different Proteins. Fresh frozen Tissues are essential for Biomarker Research and successful in-vitro Diagnostic Development. All Tissues provided by in.vent are of the highest Quality and have been meticulously validated. Tissues provided by in.vent are suitable for Extraction of various parameters.

## Assays Development

The assay development of in.vent consists of order – and in-house development. These coated tubes, ELISA and rapid tests are based on the detection by luminescence, enzyme or nanoparticles and allows the determination of proteins, antibodies or PCR products from urine, serum or whole blood.



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

# Services

## Enhanced Biobanking

Enhanced Biobanking® by in.vent takes into consideration that the key prerequisites for successful development of diagnostics are patient samples with reliable clinical data and highest 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 pre-analytics, donating and processing schemes. Enhanced Biobanking® takes into consideration these odds and guarantees customised samples in accordance with customer's requirements.

- all variations of quality & number of samples
- disease specific biobanks | disease overlapping in collections
- clinically defined, parameter oriented & medication related
- materials: sera, plasmas, human tissues, faeces and more
- ethnically controlled, age & gender monitored

## Contract Development

in.vent offers the whole range of solid phase and liquid phase of IVDs for human, animal and companion diagnostics up to bio safety level 2 using:

- Enzyme-linked Immunosorbent Assay (ELISA)
- Luminescence Assay (LUMI)
- Lateral flow Assay

**in.vent** develops new biomarkers for diagnostic and therapeutic purposes (companion diagnostics).

## Storage & Delivery

Trustworthy cold storage and reliable just in time delivery are two of the most important topics within the value chain of IVDs. Therefore in.vent offers competent, highly experienced and dependable services. Full service storage and logistics are provided for all kind of Human Biomaterials as well as for all kind of IVD kits.

in.vent offers storage at the following temperature ranges:

- +2 to +8°C
- -25 to -18°C
- -82 to -78°C
- liquid nitrogen

Standard storage of samples is ≤ -18°C.

Variations range from room temperature to storage in liquid nitrogen according to individual project needs.

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



# in.vent Clinical Services

## The key to CE: in.vent Clinical Services (ICS)

Before any IVD can be legally sold within the EU it needs to be CE-certified. To acquire a CE-certificate manufacturers must present clinical evidence that proves that the respective IVD fulfils European performance and safety requirements. In short, your assay needs to be validated.

The generation of the necessary clinical data, the compliance with all applicable legal regulations (e.g. IVDR 2017/746, Common Technical Specifications 2009/108/EC, ISO 20916) and ethical standards (e.g. Declarations of Helsinki and Taipei) is a complicated process that can be a challenge even for large international companies.

We at ICS can solve this problem for you!

ICS is the newest expansion of our service portfolio. We have harnessed our 20 years of expertise in diagnostic studies to conceive a new level of IVD-services: A complete all-round package covering every step of diagnostic assay validation! We will guide you through the entire way towards CE-certification.



### Planning and study design:

European law requires you to submit a Performance Evaluation Plan, illustrating every detail of your study design. We will develop and generate this plan for you, compliant to all applicable regulations.

### Performance studies:

The main obstacles between you and the CE-mark are the Analytical and Clinical Performance Studies. Our experts will plan, conduct, and evaluate the challenging studies profiting from our company-owned Study Site.

### Samples:

No study without samples! in.vent Diagnostica GmbH is the No.1 source for human biosamples in the EU. We can comply even with the highly demanding sample-requirements for Performance Evaluation.

### Reporting:

Before issuing the CE-certificate a Notified Body will critically review all your clinical evidence, condensed in the Performance Evaluation Report. The report we write for you will guarantee a successful review!



## Diagnostic Studies from A to Z



## Pricing

Our standard service offer comes in **five levels** (Sprint, Basic, Basic+, Pro, and Premium) which differ in project complexity. Please see below for details and prices. Product-specific deviations from these standards are of course possible and encouraged.

	ICS Sprint	ICS Basic	ICS Basic+	ICS Pro	ICS Premium
Retrospective sample set*	✓	✓	✓	✓	✓
Study plan	✓	✓	✓	✓	✓
Study evaluation	✓	✓	✓	✓	✓
Study report	✓	✓	✓	✓	✓
Prospective sample set**		✓	✓	✓	✓
Ethical clearance			✓	✓	✓
Sample size upgrade 500***				✓	✓
Sample size upgrade 1000****					✓
IVDR-compliance warranty				✓	✓

\* Leftover samples with limited clinical background. 100 negative, 100 positive samples.

\*\* Samples collected project-specifically from individuals representing the intended target population of the index test. 150 prospective samples are included in this set.

\*\*\* Number of prospective samples increased to 500

\*\*\*\* Number of prospective samples increased to 1000

Service level	Price	Timeline
ICS Sprint	48,400 €	3 months
ICS Basic	95,900 €	4.5 months
ICS Basic+	115,800 €	6 months
ICS Pro	204,000 €	9 months
ICS Premium	322,600 €	12 months

# Human Biomaterials – Normals

# 1

The **in.vent Panels of Normal Donors** are designed for the use throughout the whole value chain of in-vitro diagnostic test kits, e.g. for R&D and Quality Control Departments.

The **in.vent Panels of Normal Donors** are used for Production Purposes. The Samples consist of native Human Biomaterial with no additives.

**Normal donors** are defined to be “normal” according the German Transfusion Act. The following criteria have to be fulfilled for donation of blood, not including plasmapheresis:

Criterion	Requirement
1. Anamnesis with initial physical examination by a physician	
2. Leucocytes, Erythrocytes, Thrombocytes, mean corpuscular volume (MCV)	normal
3. Hemoglobin or Hematokrit	female: HB > 125g/l or HKT > 38% male: HB > 135g/l or HKT > 40%
4. Age	18-68 years, special criteria for exceptions > 68 years
5. Weight	minimum 50 kg
6. Blood pressure	systolic: 100-180 mm Hg diastolic: < 100 mm Hg
7. Pulse	no clinical signs, frequency 50-100/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 e.g.: neurologic diseases, cardiovascular diseases, malignant neoplasm, allergies. Potentially infected donors are excluded as well in case they are infected with HIV I or HIV II, HBV, HCV, HTLV type I or type II, protozoonosis diseases or syphilis. Potential donors who consume drugs, abnormal volumes of alcohol or abuse therapeutics are excluded as well as further high risk groups. Further details are listed in the document named above.

## Blood Products by in.vent

### Whole Blood

Whole Human Blood from standard blood donation including all physiologically occurring blood components like cells, proteins and other components.

Further Specifications:

- venous, arterial or capillary
- with anticoagulant additives possible like lithium heparin, EDTA, sodium citrate
- selection of particular donor groups (e.g. age, gender and lifestyle habits)

We offer fresh blood service with **express delivery** refrigerated or fresh frozen. Blood drawings are possible in small, medium and large volumes.

### Plasma

Centrifuged whole blood without blood cells (erythrocytes, thrombocytes, leukocytes).

Examples:

- sodium citrate plasma for coagulation tests
- lithium heparin plasma for clinical chemistry
- sodium fluoride plasma for determination of lactate and glucose

### Serum

True human serum off the clot: naturally coagulated blood, no anticoagulants.

Samples for a variety of parameter analysis:

- minerals
- hormones
- proteins
- vitamins
- enzymes



# Human Biomaterials – Normal Plasma

# 1

The **in.vent** Pools and Bulks of Normal Human Plasma are suitable for Production of Standards and Control Materials. The **in.vent** Pools and Bulks of Normal Human Plasma - Cell Culture Quality are intended to be used in Production Departments for Standards or Controls and for Cell Culture Techniques.

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

Product Number	Trade Name	Volume	Content
NDPO.P 3.1.21.1	CPD Pool	1.0l	pool of CPD donations, not further specified
NDPO.P 3.1.21.19	CPD Pool	100ml	pool of CPD donations, not further specified
NDPO.P 3.1.21.2	CPD Pool - Gender Mix	1.0l	pool of CPD donations, 50% female – 50% male donors
NDPO.P 3.1.21.29	CPD Pool - Gender Mix	100ml	pool of CPD donations, 50% female – 50% male donors
NDPO.P 3.1.21.4	CPD Pool - Gender Female	1.0l	pool of CPD donations, 100% female donors
NDPO.P 3.1.21.49	CPD Pool - Gender Female	100ml	pool of CPD donations, 100% female donors
NDPO.P 3.1.21.3	CPD Pool - Male	1.0l	pool of CPD donations, 100% male donors
NDPO.P 3.1.21.39	CPD Pool - Male	100ml	pool of CPD donations, 100% male donors
NDPO.P 3.1.21.7	CPD Pool - AB Male	1.0l	pool of CPD donations, 100% male donors
NDPO.P 3.1.21.79	CPD Pool - AB Male	100ml	pool of CPD donations, 100% male donors
NDPO.P 3.1.21.9	CPD Pool - Low Triglycerides	1.0l	pool of CPD donations, gender not specified, with low titers of triglycerides
NDPO.P 3.1.21.99	CPD Pool - Low Triglycerides	100ml	pool of CPD donations, gender not specified, with low titers of triglycerides
NDPO.P 3.1.21.6	CPD Pool – AB Mix	1.0l	pool of CPD donations, 50% female – 50% male donors
NDPO.P 3.1.21.69	CPD Pool – AB Mix	100ml	pool of CPD donations, 50% female – 50% male donors
NDPO.P 3.1.21.CS	Customised CPD Plasma Pool		“Customised CPD Plasma Pool” is exclusively derived by customers projects. Please send specifications for an individualised offer.

### Additional Information

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



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

Product Number	Trade Name	Content
NDBU.M 3.1.21.1	CPD Plasma Single Donation	CPD donation, not further specified
NDBU.M 3.1.21.4	CPD Single Donation Female	CPD donation, female donor
NDBU.M 3.1.21.3	CPD Single Donation Male	CPD donation, male donor
NDBU.M 3.1.12.CS	Customised CPD Plasma Single Donation	“Customised CPD Plasma Single Donation” is exclusively derived by customers projects. Please send specifications for an individualised offer.

### Additional Information

Matrix	Normal Human Citrate-Phosphate-Dextrose Plasma (CPD Plasma) in cell culture quality
Volume per Sample	up to 250ml, different volumes on request
Filtration	the product is filtered: 0.2µm
Disease State Testing	tested by CE-marked test systems and found negative for HIV I/II antibodies, HBsAg, HCV antibodies
Delivered Information on Certificate	product number, matrix, volume, minimum shelf life, result of laboratory testing (if applicable)

### More requirements? Send us these via:

[inquiry.inventdiagnostica.de](mailto:inquiry.inventdiagnostica.de)

# Human Biomaterials – Normal Sera

# 1

The **in.vent** Pools and Bulks of Normal Human Sera are suitable for Production of Standards and Control Materials. The **in.vent** Pools and Bulks of Normal Human Sera - Cell Culture Quality are intended to be used in Production Departments for Standards or Controls and for Cell Culture Techniques.



## Pools of Normal Human Sera

Product Number	Trade Name	Volume	Content
NDPO.P 3.1.1.1	Serum OTC Pool	1.0l	Pool of donations, not further specified
NDPO.P 3.1.1.19	Serum OTC Pool	100ml	Pool of donations, not further specified
NDPO.P 3.1.1.6	Serum OTC Pool – AB Mix	1.0l	Pool of donations, male and female
NDPO.P 3.1.1.69	Serum OTC Pool – AB Mix	100ml	Pool of donations, male and female
NDPO.P 3.1.1.4	Serum OTC Pool – Female	1.0l	Pool of donations 100% female
NDPO.P 3.1.1.49	Serum OTC Pool – Female	100ml	Pool of donations 100% female
NDPO.P 3.1.1.3	Serum OTC Pool – AB Male	1.0l	Pool of donations 100% male
NDPO.P 3.1.1.39	Serum OTC Pool – AB Male	100ml	Pool of donations 100% male
NDPO.3.1.1.CS	Customised Serum Pool		"Customised Serum Pool" is exclusively derived by customers projects. Please send specifications for an individualised offer.

### Additional Information

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

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



## Pools of Normal Human Sera – Cell Culture Quality

Product Number	Trade Name	Volume	Content
NDPO.P 3.1.11.1	Serum OTC Pool	1.0l	Pool of donations, not further specified
NDPO.P 3.1.11.19	Serum OTC Pool	100ml	Pool of donations, not further specified
NDPO.P 3.1.11.2	Serum OTC Pool – Gender Mix	1.0l	Pool of donations, 100% male and female
NDPO.P 3.1.11.29	Serum OTC Pool – Gender Mix	100ml	Pool of donations, 100% male and female
NDPO.P 3.1.11.6	Serum OTC Pool – AB Mix	1.0l	Pool of donations, male and female
NDPO.P 3.1.11.69	Serum OTC Pool – AB Mix	100ml	Pool of donations, male and female
NDPO.P 3.1.11.7	Serum OTC Pool – AB male	1.0l	Pool of donations, 100% male
NDPO.P 3.1.11.79	Serum OTC Pool – AB male	100ml	Pool of donations, 100% male
NDPO.3.1.11.CS	Customised Serum Pool		"Customised Serum Pool" is exclusively derived by customers projects. Please send specifications for an individualised offer.

### Additional Information

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



## Bulks of Normal Human Serum

Product Number	Trade Name	Content
NDBU.M 3.1.1.1	Serum OTC – Single Donations	Bulk donation, not further specified
NDBU.M 3.1.1.7	Serum OTC – Single Donations AB Male	Bulk donation, male donor
NDBU.M 3.1.1.6	Serum OTC – Single Donations AB	Bulk donation
NDBU.M 3.1.1.CS	Customised Serum OTC Single Donation	"Customised Serum OTC Single Donation" is exclusively derived by customer's projects. Please send specifications for an individualised offer.

### Additional Information

Matrix	true human serum off the clot <sup>1</sup>
Volume per Sample	up to 250 ml, different volumes on request
Disease State Testing	tested by CE-marked test systems and found negative for HIV I/II antibodies, HBsAg, HCV antibodies
Delivered Information on Certificate	product number, sample number, matrix, volume, minimum shelf life, result of infectious disease testing

### More requirements? Send us these via:

[inquiry.inventdiagnostica.de](mailto:inquiry.inventdiagnostica.de)

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

# Quality Controls & Standards



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

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

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

## in.vent Standard Quality Controls

Product Name	Analytes	Details
<b>Cardiolipin Control</b> QC.P 5.2.1.1	anti-Cardiolipin	Matrix: true human serum off the clot Levels: 1 Stability: 1 year at 2-8°C Form: lyophilised
<b>Rheumatoid Arthritis Control</b> QC.P 5.3.1.1	Rheumatoid Factor anti-CCP	Matrix: true human serum off the clot Levels: 2 Stability: 12 months at ≤ -15°C; 2 months at 2-8 °C Form: liquid
<b>Thyroid Autoantibodies Control</b> QC.P 15.2.1.1	anti-Tg anti-TPO TRAb	Matrix: true human serum off the clot Levels: 2 Stability: 5 years at 2-8°C Form: lyophilised
<b>In.QualiCheck Prostate Specific Antigen Control**</b> QC 2.1.8	PSA, total PSA, free	Matrix: true human serum off the clot Levels: 2 Stability: 4 years at 2-8°C Form: lyophilised
<b>In.QualiCheck Procalcitonin Control**</b> QC 2.1.16, QC 2.1.17, QC 2.1.18	PCT	Matrix: true human serum off the clot Levels: 3 Stability: 12 months at ≤ -15°C; 2 months at 2-8 °C Form: lyophilised
<b>In.QualiCheck Calprotectin Control**</b> QC 2.1.20, QC 2.1.21, QC 2.1.2	Calprotectin	Matrix: faeces Levels: 3 Stability: 12 months at 2-8°C Form: lyophilised
<b>Calprotectin-Elastase Control</b> QC.P 16.3.5.1	Calprotectin Elastase	Matrix: faeces Levels: 2 Stability: 12 months at 2-8°C Form: lyophilised
<b>SARS-CoV-2 IgG/IgM Serum Control</b> QC 2.1.13	SARS-CoV-2 IgG (IgM values on availability)	Matrix: true human serum off the clot Levels: 2 Stability: 6 months at 2-8°C Form: lyophilised
<b>CRP Control</b> QC 2.1.14	CRP	Matrix: true human serum off the clot Levels: 8 Stability: 12 months at 2-8°C Form: lyophilised
<b>Faecal Diagnostic – Faecal Occult Blood</b> QC 2.2.10	Haemoglobin	Matrix: faeces Levels: 2 Stability: 12 months at 2-8°C Form: lyophilised

Data sheets for each product are available on request. \* Minimum purchase: 1 batch of 500 vials, \*\* CE-certified Control

## in.vent Individual Quality Controls

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

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

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

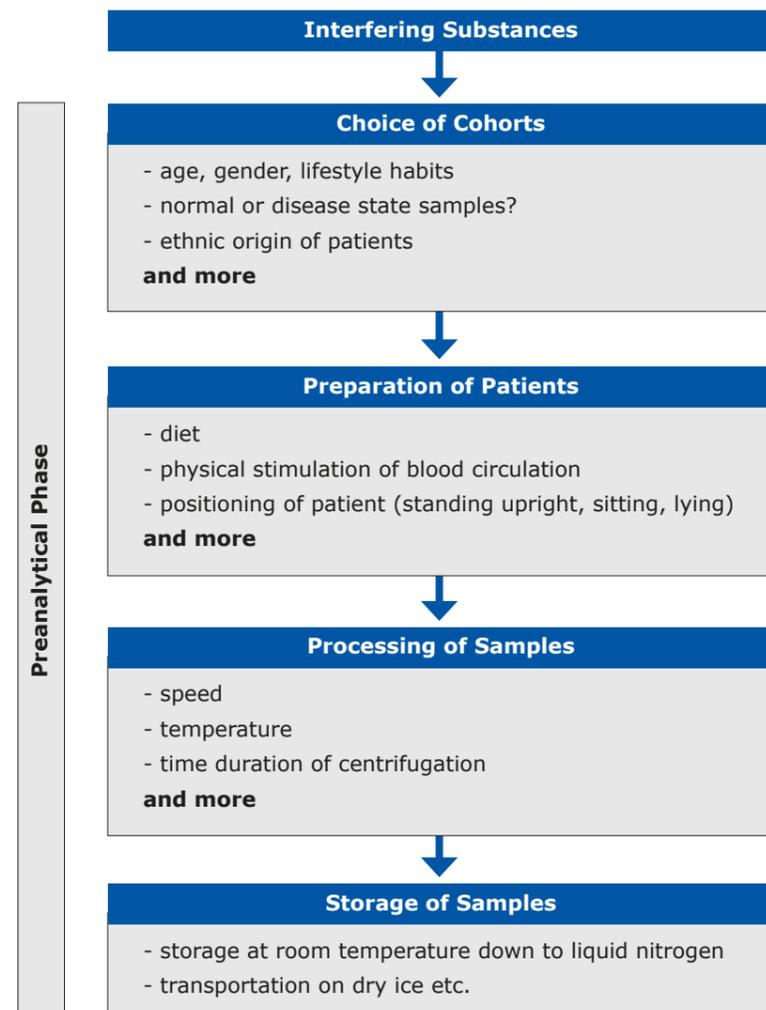
# Preanalytics

# 3

The **in.vent Panels of Preanalytics** cover a broad Range of stressed Samples, resp. Interfering Substances. The Panels are designed to be used in R&D and Quality Control Departments, mainly for study schemes regarding the Influences of different Anticoagulants and Interfering Substances on the Results of the Laboratory Testing or on Biomarkers. All Samples of the Panels of Anticoagulants are drawn under identical Conditions and donated from the identical Donor during one Single Donation.

## Examples of Interfering Substances

The generation of test results is divided into a preanalytical and an analytical phase. The preanalytical phase includes all influences that act before the measuring procedure. The analytical phase involves purely methodical and metrological conditions<sup>1</sup>.



<sup>1</sup> Klinikleitfaden Labordiagnostik

## Available Matrices

### True human Serum off the clot (OTC)

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

### K3EDTA

1.6 mg to 1.8 mg K3EDTA per ml blood is added to the tube to obtain the 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.

### K2EDTA

K2EDTA is recommended as a standard for anticoagulation in haematology of the ICSH (International Council Society of Haematology)

### Sodium Citrate

0.106 molar Sodium Citrate (equivalent to 3.2% tri-sodiumcitrate) is used to obtain plasma. An example for routine use of Sodium Citrate samples are coagulation assays like PTT or Quick test.

### Lithium Heparin

16 IU to 17 IU Lithium Heparine per ml blood, coated on granulate or added spray-dried, are used as anticoagulants to obtain the plasma. In laboratory routine Lithium Heparin samples are used for blood gas analytics or other assays in clinical chemistry.

### Ammonium Heparin (NH4 Heparin)

Ammonium Heparin plasma is known as anticoagulants in routine laboratories in end-to-end capillaries e.g.

### Sodium Heparin

17 IU Sodium Heparin per ml blood, added spray-dried, are 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.



# Preanalytics Anticoagulants

# 3

## 📋 Panels of Anticoagulants

Product Number	Trade Name	Matrices
PAPA.P 18.1.10.2	Quintet of Donors over 25 years	true serum off the clot, K3EDTA plasma, K2EDTA plasma, lithium heparin plasma, sodium citrate plasma
PAPA.P 18.1.10.3	Quintet of Donors over 65 years	true serum off the clot, K3EDTA plasma, K2EDTA plasma, lithium heparin plasma, sodium citrate plasma
PAPA.P 18.1.10.4	Quintet of Donors with BMI over 30	true serum off the clot, K3EDTA plasma, K2EDTA plasma, lithium heparin plasma, sodium citrate plasma
PAPA.P 18.3.10.1	Quintet of Donors with Diabetes	true serum off the clot, K3EDTA plasma, K2EDTA plasma, lithium heparin plasma, sodium citrate plasma
PAPA.P 18.1.10.5	Quintet of Donors without Medication Information on Certificate	true serum off the clot, K3EDTA plasma, K2EDTA plasma, lithium heparin plasma, sodium citrate plasma
PAPA.P 18.1.10.1	Quintet of Donors Normal Donors	true serum off the clot, K3EDTA plasma, K2EDTA plasma, lithium heparin plasma, sodium citrate plasma
PAPA.P 18.1.10.6	Quintet of Donors of Smoking Donors	true serum off the clot, K3EDTA plasma, K2EDTA plasma, lithium heparin plasma, sodium citrate plasma
PAPA.P 18.1.10.CS	customised specifications* – Interfering Substances	

On request also as disease state donor possible.

### Additional Information

Volume per Sample	1.0 ml, different volumes on request
Disease State Testing	on request
Delivered Information on Certificate	product number, sample number, matrix, volume, age, gender, measured result, assay system, minimum shelf life

All Panels are available as Quality Control. Please send specifications for an individualised offer.

\* "customised specifications" are specifications exclusively derived by customer's projects. Please send specifications for an individualised offer.

# Preanalytics Interfering Substances

# 3

## 📋 Panels of Interfering Substances

Product Number	Trade Name	Content
IFPA.P 18.2.10.1	Panel of Interfering Substances	Haemolysis, Bilirubin, Lipids, E.coli Antibodies, several Proteins, Rheumatoid Factor, Pregnancy
IFPA.P 18.2.10.CS	customised specifications* – Interfering Substances	

### Additional Information

Matrix	true human serum off the clot or plasma (e.g. citrate plasma)
Volume per Sample	1.0ml, different volumes on request
Panel Composition	7 vials: triglyceride-positive (lipemic) 10 vials: anti-E.coli 5 vials: 1 <sup>st</sup> trimester (1 <sup>st</sup> to 12 <sup>th</sup> week of pregnancy) 4 vials: 3 <sup>rd</sup> trimester (from 25 <sup>th</sup> week of pregnancy) 8 vials: Rheumatoid Arthritis 6 vials: haemolytic 8 vials: Bilirubin 2 vials: HAMA
Disease State Testing	on request
Delivered Information on Certificate	product number, sample number, matrix, volume, age, gender, measured result, assay system, minimum shelf life

All Panels are available as Quality Control. Please send specifications for an individualised offer.

### More requirements? Send us these via:

[inquiry.inventdiagnostica.de](mailto:inquiry.inventdiagnostica.de)

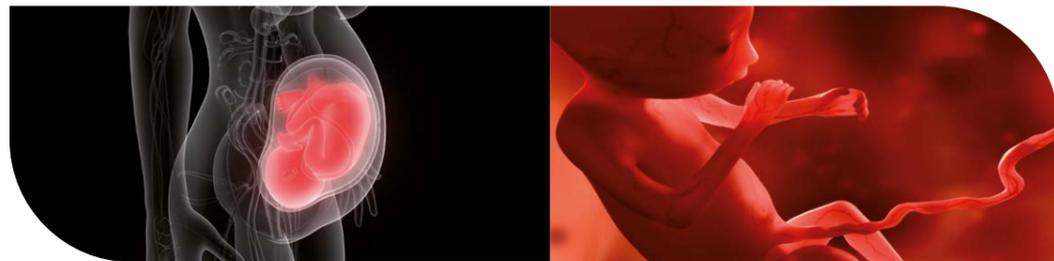
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# Fertility & Pregnancy Normals

# 4

Defined hormonal states appear due to pregnancy and fertility cycle. They are suitable to monitor changing biological states and abnormalities. Hormonal pregnancy and ovulation tests are available at low costs nearly all over the world and create great sales. Nevertheless, hormone test results and their individual consequences are often a very sensitive topic and thereby have to be extremely accurate. Worldwide contraception has already raised up to be a common topic. After using hormonal contraception there is a new trend of self-monitoring and understanding of autologous processes and a need of reports about the individual hormonal state.

The **in.vent** small volume Specimens of Normals Pregnancy are designed for the use throughout the whole value chain of in-vitro diagnostic test kits, e.g. for R&D and Quality Control Departments. The Samples consist of native Human Biomaterial with no additives. Titters are based upon Availabilities. Consecutive Donations are donated by one Donor at several Occasions. Number of Donations may vary.



## Classification Weeks of Pregnancy

Trimester	Week of Pregnancy
1 <sup>st</sup>	1 <sup>st</sup> to 12 <sup>th</sup> week of pregnancy
2 <sup>nd</sup>	13 <sup>th</sup> to 24 <sup>th</sup> week of pregnancy
3 <sup>rd</sup>	from 25 <sup>th</sup> week of pregnancy

## Small Volume Specimens of Normal Pregnancy – Single Donations

Product Number	Trade Name
DSSA.M 10.4.1.1	1st trimester of pregnancy
DSSA.M 10.5.1.1	2nd trimester of pregnancy
DSSA.M 10.6.1.1	3rd trimester of pregnancy
DSSA.M 10.14.1.4	Multiparous pregnancy
DSSA.M 10.9.1.2	Progesterone
DSSA.M 10.7.1.2	Luteinizing hormone (LH)
DSSA.M 10.11.1.4	Testosterone
DSSA.M 10.12.1.4	β-human choriongonadotropin (hCG)
DSSA.M 10.13.1.4	Follicle stimulating hormone (FSH)
DSSA.M 10.1.1.4	ACTH
DSSA.M 10.2.1.2	Dehydroepiandrosterone (DHEA)
DSSA.M 10.3.1.2	Dehydroepiandrosterone-sulfat DHEA-S

All Panels are available as Quality Control. Please send specifications for an individualised offer.

### Additional Information

Matrix	true human serum off the clot and plasma
Volume per Sample	1.0ml, different volumes on request
Delivered Information on Certificate	product number, sample number, matrix, volume, age, gender, week of pregnancy, minimum shelf life

### More requirements? Send us these via:

[inquiry.inventdiagnostica.de](mailto:inquiry.inventdiagnostica.de)

# Fertility & Pregnancy Disease State

## 4

The **in.vent** Small Volume Specimens of Pregnancy are designed for the use throughout the whole value chain of in-vitro diagnostic test kits, e. g. for R&D and Quality Control Departments. The included Diseases are related to Pregnancy (e. g. pregnancy associated diabetes). The Small Volume Specimens consist of native Human Biomaterial with no additives. Titers are based upon Availabilities.

### Small Volume Specimens of Pregnancy

Product Number	Trade Name
DSSA.M 10.8.1.2	Pregnancy Associated Diseases (AD)
DSSA.M 10.8.1.CS	Customised specifications* – Associated Diseases

#### Additional Information

Matrix	true human serum off the clot or plasma (e.g. citrate plasma)
Volume per Sample	1.0ml, different volumes on request
Delivered Information on Certificate	product number, sample number, matrix, volume, age, gender, week of pregnancy, minimum shelf life
Additional delivered Information	instruction for reconstitution for lyophilised controls

All Small Volume Specimens are available as Quality Control and Collection. Please send specifications for an individualised offer.

\* "customised specifications" are specifications exclusively derived by customer's projects. Please send specifications for an individualised offer.

# Disease State Oncology

## 5

The **in.vent** Small Volume Specimens of Oncology Biomarkers are designed for the use throughout the whole value chain of in-vitro diagnostic test kits, e. g. for R&D and Quality Control Departments. The entire range of Laboratory Test Results is represented within the Panels. The Samples consist of native Human Biomaterial with no additives. Titers are based upon Availabilities.

### Small Volume Specimens of Oncology

Product Number	Biomarker
DSSA.M 13.2.1.4	Alpha-1-Fetoprotein (AFP)
DSSA.M 13.6.1.4	Cancer-Antigen 19-9 (CA 19-9)
DSSA.M 13.5.1.4	Cancer-Antigen 125 (CA 125)
DSSA.M 13.7.1.4	Carcino Embryonic Antigen (CEA)
DSSA.M 13.12.1.4	Prostate Specific Antigen (PSA)
DSSA.M 13.4.1.2	Breast cancer Serum
DSSA.M 13.7.1.4	Carcino Embryonic Antigen (CEA)
DSSA.M 13.8.2.4	D-Dimer
DSSA.M 13.9.1.4	free Prostate Specific Antigen (fPSA)
DSSA.M 13.3.1.2	Liver Cancer Serum
DSSA.M 13.10.1.2	Myeloma Serum
DSSA.M 13.11.1.4	Neuronenspezifische Enolase (NSE)
DSSA.M 13.13.1.4	Prostate Specific Antigen (PSA)
DSSA.M 13.14.1.4	Cancer Antigen CA 15-3 (CA 15-3)

#### Additional Information

Matrix	true human serum off the clot or plasma (e.g. citrate plasma)
Volume per Sample	1.0ml, different volumes on request
Disease State Testing	on request
Delivered Information on Certificate	product number, sample number, matrix, volume, age, gender, measured laboratory result, assay system, minimum shelf life
Additional delivered Information	instruction for reconstitution for lyophilised controls

All Small Volume Specimens are available as Quality Control. Please send specifications for an individualised offer.

#### More requirements? Send us these via:

[inquiry.inventdiagnostica.de](mailto:inquiry.inventdiagnostica.de)

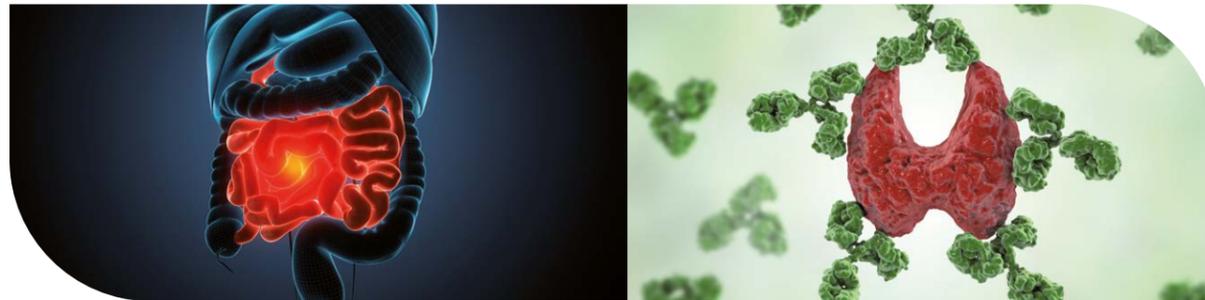
\* "customised specifications" are specifications exclusively derived by customer's projects. Please send specifications for an individualised offer.

# Disease State Autoimmune Diseases

# 5

Laboratory testing is of great value when evaluating a patient with a suspected autoimmune disease. The results can confirm a diagnosis, estimate disease severity, aid in assessing prognosis and are useful to follow disease activity. Comprehensive laboratory evaluation of a suspected autoimmune illness in conjunction with a thorough clinical evaluation provides a better understanding of a patient's immunologic disease.

The **in.vent** Bulks of Autoimmune Biomarkers and Autoimmune Diseases are designed for the use throughout the whole value chain of in-vitro diagnostic test kits, e.g. for R&D and Quality Control Departments. They are representative for different types of Autoimmune Diseases. The Bulks consist of native Human Biomaterial with no additives. Titers are based upon Availabilities.



## Bulks of Autoimmune Diseases – Biomarkers

Product Number	Corresponding Biomarkers for main Autoimmune Disease Groups
DSBU.M 5.1.1.2	ACHR
DSBU.M 5.2.1.2	ANA
DSBU.M 5.3.2.2	ANCA
DSBU.M 5.4.1.2	Anti Cyclic citrullinated peptide (a-CCP/ACPA)
DSBU.M 5.13.1.2	Myeloperoxidase (MPO)
DSBU.M 5.16.1.2	Proteinase 3 (PR3)
DSBU.M 5.18.1.29	Total Rheumatoid Factor (tRF)

### Additional Information

Matrix	true human serum off the clot <sup>1</sup> or Plasma
Volume per Sample	up to 250 ml, different volumes on request
Disease State Testing	tested by CE-marked test systems and found negative for HIV I/II antibodies, HBsAg, HCV antibodies
Delivered Information on Certificate	product number, sample number, matrix, volume, minimum shelf life, result of infectious disease testing



## Bulks of Autoimmune Diseases

Product Number	Trade Name
DSBU.M 5.5.1.2	Autoimmune Hepatitis
DSBU.M 5.6.1.2	Celiac Disease
DSBU.M 5.8.1.2	Morbus Crohn
DSBU.M 5.9.1.2	Multiple Autoimmune Diseases
DSBU.M 5.10.1.2	Multiple Myeloma
DSBU.M 5.11.1.2	Multiple Sclerosis
DSBU.M 5.12.1.2	Myasthenia gravis
DSBU.M 5.14.1.2	Pernicious Anemia (PA)
DSBU.M 5.15.1.2	Primary Biliary Cholangitis (PBC)
DSBU.M 5.17.1.2	Rheumatoid Arthritis
DSBU.M 5.21.1.2	Systemic Lupus Erythematosus (SLE)
DSBU.M 5.22.1.2	Ulcerative Colitis

### Additional Information

Matrix	true human serum off the clot <sup>1</sup> or Plasma
Volume per Sample	up to 250 ml, different volumes on request
Disease State Testing	tested by CE-marked test systems and found negative for HIV I/II antibodies, HBsAg, HCV antibodies
Delivered Information on Certificate	product number, sample number, matrix, volume, minimum shelf life, result of infectious disease testing

Available with ICD10-Code on request

### More requirements? Send us these via:

[inquiry.inventdiagnostica.de](mailto:inquiry.inventdiagnostica.de)

# Disease State Diabetes

# 5

Worldwide, approximately 425 million people suffer from diabetes. If the numbers of diabetes as feared by the IDF (International Diabetes Federation) increase, there could be about 629 million diabetics worldwide in 2045.<sup>1</sup>

## Diabetes mellitus Type I

$\beta$ -cell destruction, which leads to an absolute insulin deficiency – usually immunologically mediated.

## Diabetes mellitus Type II

Insulin resistances, with relative insulin deficiency to largely secretory defect, are often associated with other diseases (e.g., “metabolic syndrome”).



The **in.vent** Small Volume Specimens and Bulks of Biomarkers for Diabetes I and II as well as Panels of Diabetes Diseases are designed for the use throughout the whole value chain of in-vitro diagnostic test kits, e.g. for R&D and Quality Control Departments. The products consist of native Human Biomaterial with no additives. Titers are based upon Availabilities.



## Bulks of Diabetes Diseases

Product Number	Biomarker
DSBU.M 8.2.1.2	Panel Diabetes Type I
DSBU.M 8.3.1.2	Panel Diabetes Type II
DSBU.M 8.7.1.2	Panel selected Medication

### Additional Information

Matrix	true human serum off the clot or plasma (e.g. citrate plasma)
Volume per Sample	up to 250ml per single donation
Disease State Testing	tested by CE-marked test systems and found negative for HIV I/II antibodies, HBsAg, HCV antibodies
Delivered Information on Certificate	product number, sample number, matrix, volume, age, gender, measured laboratory results, assay system, minimum shelf life

All Small Volume Specimens and Bulks are available as Quality Control.

Please send specifications for an individualised offer.

\* “customised specifications” are specifications exclusively derived by customer’s projects.



## Bulks of Diabetes mellitus Type I – Biomarkers

Product Number	Biomarker
DSBU.M 8.5.1.2	Insulin Autoantibodies (IAA)
DSBU.M 8.10.1.2	Icelet Cell Antibodies (ICA)
DSBU.M 8.6.1.2	Tyrosine-Phospatase Antibodies (IA2)
DSBU.M 8.9.1.2	Glutamate-Decarboxylase Antibodies (GADA)
DSBU.M 8.2.1.CS	customised specifications* – Panels of Diabetes I

### Additional Information

Matrix	true human serum off the clot or plasma (e.g. citrate plasma)
Volume per Sample	up to 250ml per single donation
Disease State Testing	tested by CE-marked test systems and found negative for HIV I/II antibodies, HBsAg, HCV antibodies
Delivered Information on Certificate	product number, sample number, matrix, volume, age, gender, measured laboratory results, assay system, minimum shelf life



## Small Volume Specimens of Diabetes mellitus Type II – Biomarkers

Product Number	Biomarker
DSSA.M 8.8.1.2	HbA1c EDTA Whole Blood
DSSA.M 8.12.8.2	Glucosis Urine
DSSA.M 8.3.1.CS	customised specifications* – Panels of Diabetes II

### Additional Information

Matrix	true human serum off the clot or plasma (e.g. citrate plasma) or Whole Blood or Urine
Volume per Sample	1.0ml, different volumes on request
Delivered Information on Certificate	product number, sample number, matrix, volume, age, gender, measured laboratory result, assay system, minimum shelf life
Provided Levels	negative, borderline, positive

<sup>1</sup> <https://de.statista.com/themen/262/diabetes>

\* “customised specifications” are specifications exclusively derived by customer’s projects.

Please send specifications for an individualised offer.

# Disease State Infectious Diseases

# 5

**in.vent** Bulks of Infectious Diseases are Patient Samples tested positive for designated Infectious Diseases. Titers will vary according to Availability of Bulks. These Bulks are designated to be used in R&D and Quality Control Departments. The Samples consist of native Human Biomaterial with no additives.

## Specimen tested positive for Infectious Diseases

### Bulks of Infectious Diseases – Viral Parameters

Product Number	Parameters*
DSBU.M 4.1.4.3.17	Cytomegalovirus (CMV) IgG positive
DSBU.M 4.1.4.3.19	Cytomegalovirus (CMV) IgM positive
DSBU.M 4.1.4.3.25	Epstein-Barr Virus Viral Capsid Antigen (EBV: VCA) IgM positive
DSBU.M 4.1.4.3.96	Epstein-Barr Virus Early Antigen (EBV:EA) IgG positive
DSBU.M 4.1.4.3.102	Hepatitis C Virus (HCV) positive
DSBU.M 4.1.4.3.104	Hepatitis E Virus (HEV) IgM positive
DSBU.M 4.1.4.3.144	Hepatitis B Virus surface Antigen (HBsAg) positive
DSBU.M 4.1.4.3.105	Herpes simplex virus-1 (HSV-1) IgG positive
DSBU.M 4.1.4.3.106	Herpes simplex virus-1 (HSV-1) IgM positive
DSBU.M 4.1.4.3.107	Herpes simplex virus-2 (HSV-2) IgM positive
DSBU.M 4.1.4.3.108	Human Immunodeficiency Virus-1 (HIV-1) positive
DSBU.M 4.1.4.3.109	Human Immunodeficiency Virus-1/2 (HIV-1/2) positive
DSBU.M 4.1.4.3.111	Human Immunodeficiency Virus-1/2 p24 (HIV-1/2 p24) positive
DSBU.M 4.1.4.3.113	Human Immunodeficiency Virus-2 (HIV-2) positive
DSBU.M 4.1.4.3.115	Influenza A IgG positive
DSBU.M 4.1.4.3.116	Influenza A IgA positive
DSBU.M 4.1.4.3.117	Influenza B IgG positive
DSBU.M 4.1.4.3.38	Measles IgG positive
DSBU.M 4.1.4.3.122	Measles IgM positive
DSBU.M 4.1.4.3.41	Mumps IgG positive
DSBU.M 4.1.4.3.43	Mumps IgM positive
DSBU.M 4.1.4.3.126	Parainfluenza 1,2,3 IgA positive
DSBU.M 4.1.4.3.127	Parainfluenza 1,2,3 IgG positive
DSBU.M 4.1.4.3.128	Parvovirus B19 positive
DSBU.M 4.1.4.3.129	Respiratorische synzytial virus (RSV) IgG positive
DSBU.M 4.1.4.3.130	Respiratorische synzytial virus (RSV) IgM positive
DSBU.M 4.1.4.3.49	Rubella IgG positive
DSBU.M 4.1.4.3.51	Rubella IgM positive
DSBU.M 4.1.4.3.63	Varicella Zoster Virus (VZV) IgG positive
DSBU.M 4.1.4.3.65	Varicella Zoster Virus (VZV) IgM positive
DSBU.M 4.1.4.3.141	Varicella Zoster Virus (VZV) IgA positive
DSBU.M 4.1.4.3.142	Yellow Fever positive

### Bulks of Infectious Diseases – Fungal Parameters

Product Number	Parameters*
DSBU.M 4.1.4.3.15	Candida IgG positive

### Bulks of Infectious Diseases – Bacterial Parameters

Product Number	Parameters*
DSBU.M 4.1.4.3.150	Bordetella pertussis toxin IgA positive
DSBU.M 4.1.4.3.3.	Bordetella pertussis IgM positive
DSBU.M 4.1.4.3.4	Bordetella pertussis IgG positive
DSBU.M 4.1.4.3.14	Campylobacter IgM positive
DSBU.m 4.1.4.3.151	Chlamydia pneumoniae IgA positive
DSBU.M 4.1.4.3.152	Chlamydia pneumoniae IgG positive
DSBU.M 4.1.4.3.87	Chlamydia pneumoniae IgM positive
DSBU.M 4.1.4.3.12	Chlamydia trachomatis IgG positive
DSBU.M 4.1.4.3.13	Chlamydia trachomatis IgM positive
DSBU.M 4.1.4.3.89	Coxiella burnetii (Phase II) IgG positive
DSBU.M 4.1.4.3.90	Coxiella burnetii (Phase II) IgM positive
DSBU.M 4.1.4.3.92	Diphtheria IgG positive
DSBU.M 4.1.4.3.99	Helicobacter pylori IgA positive
DSBU.M 4.1.4.3.101	Helicobacter pylori IgG positive
DSBU.M 4.1.4.3.118	Leishmania IgG positive
DSBU.M 4.1.4.3.36	Leptospira IgG positive
DSBU.M 4.1.4.3.123	Mycoplasma pneumoniae IgG positive
DSBU.M 4.1.4.3.124	Mycoplasma pneumoniae IgM positive
DSBU.M 4.1.4.3.125	Mycoplasma ssp. IgA positive
DSBU.M 4.1.4.3.132	Syphilis (Treponema pallidum) positive
DSBU.M 4.1.4.3.139	Ureaplasma urealyticum IgG positive
DSBU.M 4.1.4.3.140	Ureaplasma urealyticum IgM positive

### Bulks of Infectious Diseases – Parasitological Parameters

Product Number	Parameters*
DSBU.M 4.1.4.3.148	Ascaris lumbricoides IgG positive
DSBU.M 4.1.4.3.27	Echinococcus IgG positive
DSBU.M 4.1.4.3.94	Entamoeba histolytica IgG positive
DSBU.M 4.1.4.3.97	Fasciola hepatica IgG positive
DSBU.M 4.1.4.3.98	Filaria positive
DSBU.M 4.1.4.3.120	Malaria (Plasmodium ssp.) IgM/IgG positive
DSBU.M 4.1.4.3.146	Malaria Antigen positive
DSBU.M 4.1.4.3.58	Schistosoma IgG positive
DSBU.M 4.1.4.3.131	Strongyloides IgG positive
DSBU.M 4.1.4.3.134	Taenia solium IgG positive
DSBU.M 4.1.4.3.136	Toxocara canis IgG positive
DSBU.M 4.1.4.3.138	Toxoplasma gondii IgA positive
DSBU.M 4.1.4.3.59	Toxoplasma gondii IgG positive
DSBU.M 4.1.4.3.61	Toxoplasma gondii IgM positive

#### Additional Information

Matrix	true human serum off the clot or plasma (e.g. citrate plasma)
Volume per Sample	up to 250 ml per single donation
Disease State Testing	tested by CE-marked test systems and found negative for HIV I/II antibodies, HBsAg, HCV antibodies
Delivered Information on Certificate	product number, sample number, matrix, volume, age, gender, measured laboratory results, assay system, minimum shelf life

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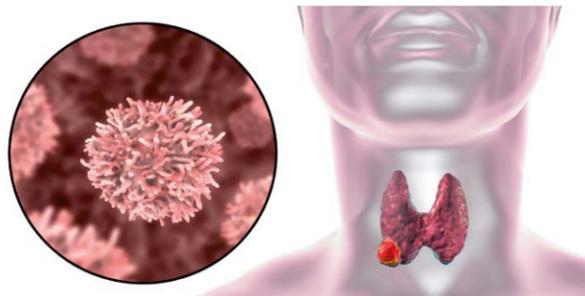
# Disease State Thyroid Diseases

# 5

Worldwide hypothyroidism and goiter are the most common forms due to dietary iodine deficiency and affects 3-10% of adults. One third of world's population currently lives in areas of low dietary iodine levels. In regions of severe iodine deficiency, the prevalence of goiter is up to 80%. In areas without iodine-deficiency, autoimmune diseases as Hashimoto's thyroiditis have the highest prevalence (1-2%).

For Hyperthyroidism Graves' disease is the most common type with a prevalence of 0,5-3%. Although thyroid nodules are common, thyroid cancer is rare though it is the most common endocrine tumor and makes up greater than 90% of all cancers of the endocrine glands.

The **in.vent** Bulks of Biomarkers for Thyroid Diseases are designed for the use throughout the whole value chain of in-vitro diagnostic test kits, e.g. for R&D and Quality Control Departments. The Samples consist of native Human Biomaterial with no additives. Titers are based upon Availabilities.



## Bulks sorted by Thyroid Biomarkers

Product Number	Biomarker
DSBU.M 15.3.1.2	anti-Tg
DSBU.M 15.2.1.2	anti-TPO
DSBU.M 15.5.4.2	anti-TSH Receptor
DSBU.M 15.5.1.2	TSH
DSBU.M 15.2.1.CS	customised specifications* – Thyroid Diseases – Biomarkers

### Additional Information

Matrix	true human serum off the clot or plasma (e.g. citrate plasma)
Volume per Sample	up to 250ml per single donation
Disease State Testing	tested by CE-marked test systems and found negative for HIV I/II antibodies, HBsAg, HCV antibodies
Delivered Information on Certificate	product number, sample number, matrix, volume, age, gender, measured laboratory results, assay system, minimum shelf life



## Bulks sorted by Thyroid Diseases

Product Number	Biomarker
DSBU.M 15.17.1.2	Hashimoto's Thyroiditis
DSBU.M 15.7.1.2.	Hyperthyroidism
DSBU.M 15.18.1.2	Hypothyroidism
DSBU.M 15.9.1.2	Graves' Disease
DSBU.M 15.3.1.CS	customised specifications* – Thyroid Diseases

### Additional Information

Matrix	true human serum off the clot or plasma (e.g. citrate plasma)
Volume per Sample	up to 250ml per single donation
Disease State Testing	tested by CE-marked test systems and found negative for HIV I/II antibodies, HBsAg, HCV antibodies
Delivered Information on Certificate	product number, sample number, matrix, volume, age, gender, measured laboratory results, assay system, minimum shelf life

All Bulks are available as Quality Control. Please send specifications for an individualised offer.

### More requirements? Send us these via:

[inquiry.inventdiagnostica.de](mailto:inquiry.inventdiagnostica.de)

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# Disease State Inflammation

# 5

A huge variety of inflammatory parameters is available for diagnostic of inflammatory diseases. Differentiated immunological tests give detailed information about activity and state of the immune system. In contrast for routine diagnostics and disease monitoring especially for septic patients and serious infections only few laboratory parameters are suitable for clinical inflammatory monitoring.

Procalcitonin (PCT) as a specific and reliable marker for serious bacterial infections and their complications caused by systemic inflammation. PCT reacts at sepsis, shock and in presence of serious systemic inflammatory diseases and allows an assured monitoring.<sup>1</sup>

The **in.vent** Bulks of Biomarkers for PCT is designed for the use throughout the whole value chain of in-vitro diagnostic test kits, e.g. for R&D and Quality Control Departments. The Bulks consist of native Human Biomaterial with no additives. Titrers are based upon Availabilities.



<sup>1</sup> „Procalcitonin (PCT)“, Michael Meisner



## Bulks of Inflammation – Biomarkers

Product Number	Biomarker
DSBU.M 14.3.1.3	CRP negative negativ
DSBU.M 14.3.1.2	CRP positive positiv
DSBU.M 14.3.1.25	CRP highly positive
DSBU.M 14.4.1.3	Serumamyloid A (SAA), negative
DSBU.M 14.4.1.2	Serumamyloid A (SAA), positive
DSBU.M 14.4.1.25	Serumamyloid A (SAA), highly positive
DSBU.M 14.2.1.2	PCT positive

### Additional Information

Matrix	true human serum off the clot or plasma (e.g. citrate plasma)
Volume per Sample	up to 250ml per single donation
Disease State Testing	tested by CE-marked test systems and found negative for HIV I/II antibodies, HBsAg, HCV antibodies
Delivered Information on Certificate	product number, sample number, matrix, volume, age, gender, measured laboratory results, assay system, minimum shelf life

All Bulks are available as Quality Control. Please send specifications for an individualised offer.

### More requirements? Send us these via:

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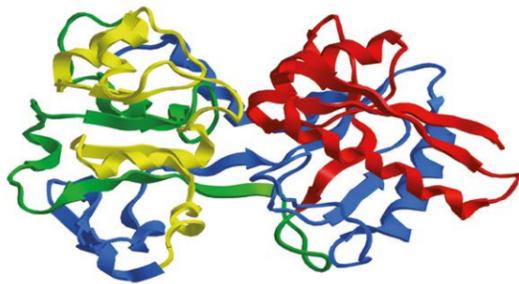
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# Disease State Drugs of Abuse

# 5

Abuse of alcohol means to be a social and economical problem and thereby is poorly detectable by using anamnetic data. Carbohydrate Deficient Transferrin (CDT) is a specific and commonly accepted biochemical marker to objectively detect chronic abuse of alcohol. Permanent abuse of alcohol leads to abnormal isoforms of Transferrin (CDT) by influencing the transferrin biosynthesis.<sup>1</sup>

The **in.vent** Small Volume Specimens and Pools of Carbohydrate Deficient Transferrin (CDT) are designed for the use throughout the whole chain of in-vitro diagnostic test kits, e.g. for R&D and Quality Control Departments. The Samples consist of native Human Biomaterial with no additives. Titers are based upon Availabilities.



Structure of Carbohydrate  
Deficient Transferrin (CDT)

<sup>1</sup> Klinikleitfaden Labordiagnostik

## Small Volume Specimens of Carbohydrate Deficient Transferrin (CDT)

Product Number	Biomarker	Volume
DSSA.M 9.2.2.2	CDT Plasma	1 ml
DSSA.M 9.2.1.2	CDT Serum	1 ml

### Additional Information

Matrix	true human serum off the clot or plasma (e.g. citrate plasma)
Volume per Sample	1.0 ml, different volumes on request
Delivered Information on Certificate	product number, sample number, matrix, volume, age, gender, measured laboratory result, assay system, minimum shelf life
Measured Laboratory Markers	Carbohydrate Deficient Transferrin (CDT) measured by High Performance Liquid Chromatography (HPLC)

All Small Volume Specimens are available as Quality Control. Please send specifications for an individualised offer.



## Pools of Carbohydrate Deficient Transferrin (CDT)

Product Number	Biomarker	Volume
DSPO.P 9.2.10.2	CDT Pool	1.0 l
DSPO.P 9.2.10.9	CDT Pool	100 ml
DSPO.P 9.2.10.CS	customised specifications* – CDT – Pools	

### Additional Information

Matrix	true human serum off the clot or plasma (e.g. citrate plasma)
Disease State Testing	tested by CE-marked test systems and found negative for HIV I/II antibodies, HBs antigen, HCV antibodies
Delivered Information on Certificate	product number, sample number, matrix, volume, age, gender, measured laboratory result, assay system, minimum shelf life
Measured Laboratory Markers	Carbohydrate Deficient Transferrin (CDT) measured by High Performance Liquid Chromatography (HPLC)

### More requirements? Send us these via:

[inquiry.inventdiagnostica.de](mailto:inquiry.inventdiagnostica.de)

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# Disease State Allergy

# 5

The **in.vent** Bulks of Allergy are designed for the use throughout the whole value chain of in-vitro diagnostic test kits, e.g. for R&D and Quality Control Departments. They are representative for different Allergens. The Samples consist of native Human Biomaterial with no additives. Titers are based upon Availabilities.



## Pools of Allergy

Product Number	Biomarker
DSPO.M 4.3.10.2	total IgE
DSPO.M 4.2.10.2	specific IgE

### Additional Information

Matrix	true human serum off the clot or plasma (e.g. citrate plasma)
Disease State Testing	tested by CE-marked test systems and found negative for HIV I/II antibodies, HBs antigen, HCV antibodies
Delivered Information on Certificate	product number, sample number, matrix, volume, age, gender, measured laboratory result, assay system, minimum shelf life

## Bulks of Allergy - total IgE

Product Number	Biomarker
DSBU.M 4.3.1.2	total IgE
DSBU.M 4.3.1.CS	customised specifications* – total IgE – Bulks

### Additional Information

Matrix	true human serum off the clot or plasma (e.g. citrate plasma)
Volume per Sample	up to 250ml, different volumes on request
Disease State Testing	tested by CE-marked assay systems and found negative for HIV I/II antibodies, HBs antigen, HCV antibodies
Delivered Information on Certificate	product number, sample number, matrix, volume, age, gender, measured laboratory result, assay system, minimum shelf life
Provided Titer	negative, normal, borderline, positive

\* "customised specifications" are specifications exclusively derived by customer's projects. Please send specifications for an individualised offer.

## Bulks of Allergy - specific IgE

Available in Serum and Plasma

Product Number	Biomarker	Product Number	Biomarker
DSBU.M 4.4.1.2	CCD	DSBU.M 4.36.1.2	f76
DSBU.M 4.5.1.2	d1	DSBU.M 4.37.1.2	f77
DSBU.M 4.6.1.2	d2	DSBU.M 4.38.1.2	f78
DSBU.M 4.7.1.2	e1	DSBU.M 4.39.1.2	f84
DSBU.M 4.8.1.2	e2	DSBU.M 4.40.1.2	f85
DSBU.M 4.9.1.2	e204	DSBU.M 4.41.1.2	f88
DSBU.M 4.10.1.2	e3	DSBU.M 4.42.1.2	f9
DSBU.M 4.11.1.2	e5	DSBU.M 4.43.1.2	f94
DSBU.M 4.12.1.2	f1	DSBU.M 4.44.1.2	f95
DSBU.M 4.13.1.2	f10	DSBU.M 4.45.1.2	g1
DSBU.M 4.14.1.2	f13	DSBU.M 4.46.1.2	g12
DSBU.M 4.15.1.2	f14	DSBU.M 4.47.1.2	g17
DSBU.M 4.16.1.2	f17	DSBU.M 4.48.1.2	g2
DSBU.M 4.17.1.2	f199	DSBU.M 4.49.1.2	g201
DSBU.M 4.18.1.2	f2	DSBU.M 4.50.1.2	g3
DSBU.M 4.19.1.2	f20	DSBU.M 4.51.1.2	g6
DSBU.M 4.20.1.2	f23	DSBU.M 4.52.1.2	h1
DSBU.M 4.21.1.2	f237	DSBU.M 4.53.1.2	i3
DSBU.M 4.22.1.2	f24	DSBU.M 4.54.1.2	i6
DSBU.M 4.23.1.2	f25	DSBU.M 4.55.1.2	k82
DSBU.M 4.24.1.2	f27	DSBU.M 4.56.1.2	m1
DSBU.M 4.25.1.2	f3	DSBU.M 4.57.1.2	m2
DSBU.M 4.26.1.2	f31	DSBU.M 4.58.1.2	m3
DSBU.M 4.27.1.2	f320	DSBU.M 4.59.1.2	m6
DSBU.M 4.28.1.2	f33	DSBU.M 4.60.1.2	t2
DSBU.M 4.29.1.2	f35	DSBU.M 4.61.1.2	t23
DSBU.M 4.30.1.2	f4	DSBU.M 4.62.1.2	t3
DSBU.M 4.31.1.2	f41	DSBU.M 4.63.1.2	t4
DSBU.M 4.31.2.2	f44	DSBU.M 4.64.1.2	t7
DSBU.M 4.32.1.2	f45	DSBU.M 4.65.1.2	t9
DSBU.M 4.33.1.2	f49	DSBU.M 4.66.1.2	w1
DSBU.M 4.34.1.2	f5	DSBU.M 4.67.1.2	w6
DSBU.M 4.35.1.2	f75	DSBU.M 4.68.1.2	w9

### Additional Information

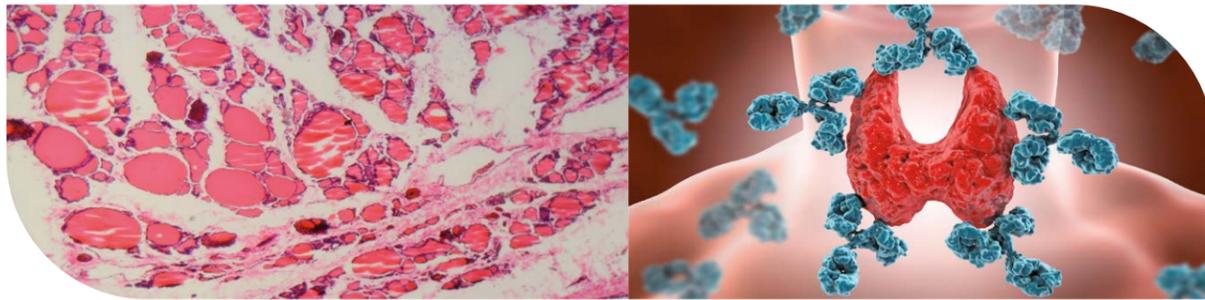
Matrix	true human serum off the clot or plasma (e.g. citrate plasma)
Volume per Sample	up to 250ml, different volumes on request
Disease State Testing	tested by CE-marked assay systems and found negative for HIV I/II antibodies, HBs antigen, HCV antibodies
Delivered Information on Certificate	product number, sample number, matrix, volume, age, gender, measured laboratory result, assay system, minimum shelf life

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# Human Tissues & Specialities

# 6

**in.vent** provides raw Human Materials for further processing such as tissues or extracts and smart matrices such as saliva or application-specific matrices such as urine or faeces. All Tissues & Specialties are of the highest quality and offered in a routine and professional manner for special diagnostic scopes and development of smart new assays.



## Thyroid Tissues

Product Number	Product
TSSA.M 19.3.9.1	Thyroid Tissue- small undefined samples without testing, fresh frozen
TSPO.P 19.3.9.2	Thyroid Tissue- small undefined samples without testing, fresh frozen, pooled
TSSA.M 19.3.9.29	Human Thyroid Tissue: <5g, without viral testing
TSSA.M 19.3.9.2	Human Thyroid Tissue: >5g, viral testing negative

## Cancer Tissue

Product Number	Product
TSSA.M 19.2.9.2	Cancer Tissue

## Human Saliva

Product Number	Product
TSSA.M 19.1.7.1	Normal Saliva
TSSA.M 19.2.7.2	SARS-CoV-2 positive Saliva

## Human Urine

Product Number	Product
TSSA.M 19.1.8.1	Normal Urine
TSSA.M 19.2.8.2	Amylase Urine

## Human Faeces

Product Number	Product
TSSA.M 19.1.5.1	Normal Faeces, 1g
TSSA.M 19.2.5.2	Pancreatic Elastase
TSSA.M 19.3.5.2	Calprotectin
TSSA.M 19.4.5.2	Hemoglobin
TSSA.M 19.5.5.2	H.pylori

## Swabs & Misc.

Product Number	Product
TSSA.M 19.1.4.1	Normal swab* **
TSSA.M 19.2.4.2	SARS-CoV-2 positive swabs* **
TSSA.M 19.3.4.2	Influenza A positive swabs* **
TSSA.M 19.4.4.2	Influenza B positive swabs* **
TSSA.M 19.2.12.2	PCR positive SARS-CoV-2 RNA extract

\* dry swabs, swabs in activated or inactivated viral transport medium (VTM), VTM without swabs

\*\* professional and non-professional sampling

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## Imprint

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# Human Biomaterials



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