

We are human

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

Human Bio-Materials

Extract of our Portfolio
2020/21



Contact & Ordering Information



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We keep you up to date!

www.inventdiagnostica.de

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 2001.

in.vent is focussed on the customised procurement of Human Bio-Materials. 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 Bio-Materials worldwide and is first contact for chinese market. 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.

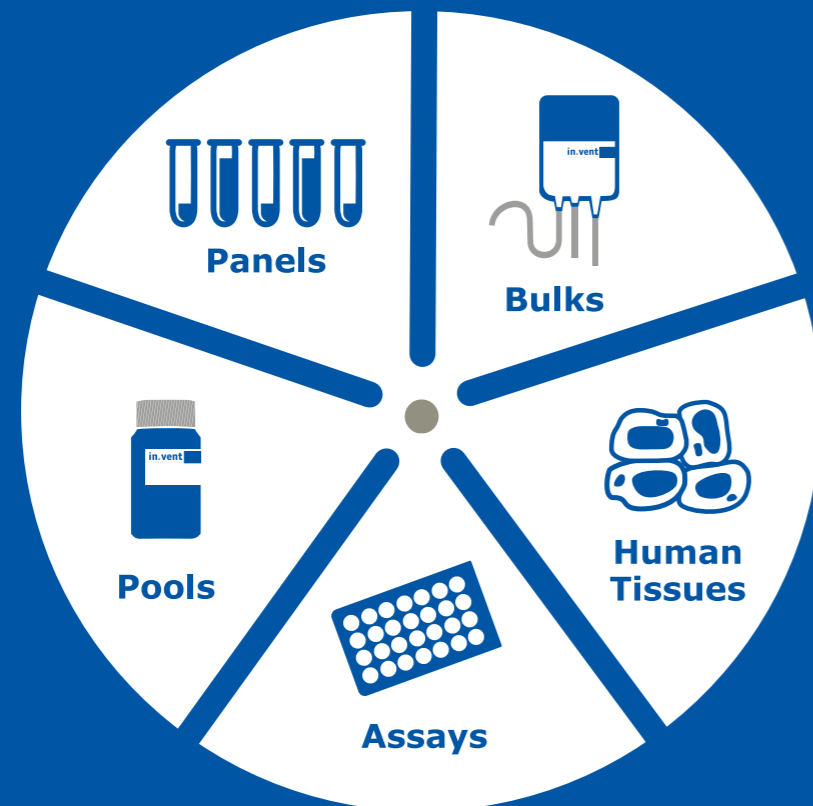
in.vent's clients profit from the team of high qualified scientists with extensive and deep knowledge of Human Bio-Materials and its thorough understanding of assay development.

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.



Product Overview

Panels:

- samples off-the-shelf, prospective collections and customised samples
- wide range of different biomarkers and controls and multiple matrices

Bulks:

- standard and customised bulks of different biomarkers and matrices
- up to 250 ml

Pools:

- standard and customised of different biomarkers and matrices
- up to thousands of litres

Assays:

- in-house development
- based on the detection by luminescence, enzyme or nanoparticles
- determination of proteins, antibodies or PCR products from urine, serum or whole blood

Human Tissues:

- suitable for extraction of various parameters
- fresh frozen

The complexity of your requirements is our standard.

Ethical Principles and Values of in.vent

in.vent is committed to the highest international ethical and legal standards and always observes the principles of the Declarations of Helsinki and Taipei as defined by the World Medical Association in all projects. Our medical cooperation partners are contractually committed and complying with these standards. Our projects are evaluated by competent independent ethics committees and, if necessary, by the competent federal authority.

In doing so, we take into account: the notes of the Federal Medical Association and the "Working Group of Medical Ethics Committees in the Federal Republic of Germany e.V.", the Europe-wide General Data Protection Regulation, ISO 20916 (in-vitro diagnostic medical devices – Clinical performance studies using specimens from human subjects – Good study practice) and ISO 20387 (Biotechnology – Biobanking – General requirements for biobanking) and are thus able to fully comply with the ethical principles required by IVDR 2017/746.



Beyond samples: 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/FDIS 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!**

With ICS you profit from our experience during 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:
We roughly stratify our price range into three categories: **simple, average, and complex** projects.

Simple:
starting at **80,000 €**

Average:
starting at **200,000 €**

Complex:
starting at **350,000 €**

Please note that these prices are only very rough estimations and by no means binding. Study design is a highly complex process and depends on a plethora of factors, such as the exact intended purpose of the IVD, whether residual samples can be used for the validation, whether an ethics committee needs to be consulted, etc.

Therefore: **Please enquire!**

We will provide you with a time and cost estimation for your individual validation project as quick as we can!

Your direct contact:
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+49 3302 55199 550
Website: ics.bio

Sales off the Shelf

1 Human Bio-Materials – Normals

Product Number	Product Name	Pricing	Availability
NDPO 4.2.1.1	CPD Pool 1.0 l	600.00 €/l	immediately
NDBU 4.2.2.1	CPD Plasma Single Donation	250.00 €/bulk	immediately
NDPO 4.2.3.1	Serum OTC Pool 1.0 l	1,650.00 €/l	immediately

Data sheets for each product are available on request.

2 Preanalytics

Product Number	Product Name	Pricing	Availability
NDSA 4.3.1.1	Quintet of Donors with BMI over 30	200.00 €/quintet	immediately
NDSA 4.3.1.2	Quintet of Normal Donors	200.00 €/quintet	immediately
NDSA 4.3.1.3	Quintet of Donors over 65 years	200.00 €/quintet	immediately
NDSA 4.3.1.4	Quintet of Donors over 25 years	200.00 €/quintet	immediately
NDSA 4.3.1.5	Quintet of Smoking Donors	200.00 €/quintet	immediately
NDSA 4.3.1.6	Quintet of Donors without Medication	200.00 €/quintet	immediately
DSSA 4.1.3.2.4	Quintet of Donors with Diabetes	200.00 €/quintet	immediately
NDSA 4.3.1.7	Normal Serum Triplet	200.00 €/triplet	immediately
IFPA 4.5.1.1	Panels of Interfering Substances	800.00 €/panel	immediately
IFPA 4.5.2.1	Cortisol Panel	300.00 €/panel	immediately
IFPA 4.5.2.2	High Density Lipoprotein Panel	300.00 €/panel	immediately
GEPA 4.8.1.1	Gerontology Panel	800.00 €/panel	immediately
ADPA 4.1.1.1	Obesity Panel	800.00 €/panel	immediately

Each panel consists of 10 samples (volume per sample: 1.0 ml, different volumes on request).

Data sheets for each product are available on request.

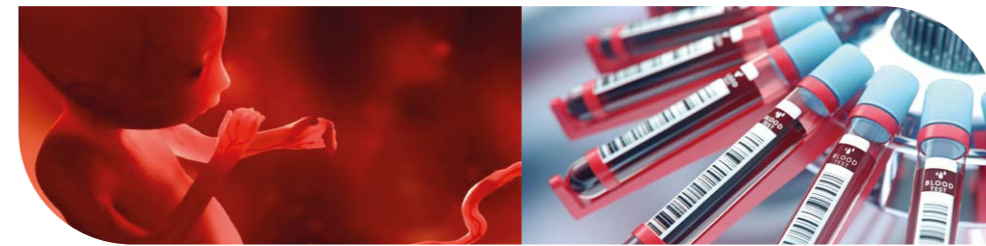


3 Quality Controls & Standards

Product Number	Product Name	Pricing*	Availability
QC 2.1.1	Cardiolipin Control	15.00 €/vial	immediately
QC 2.1.2	Rheumatoid Arthritis Control	23.00 €/vial	immediately
QC 2.1.4	Thyroid Autoantibodies Control	25.00 €/vial	immediately
QC 2.1.10	Prostate Specific Antigen Control	28.00 €/vial	immediately
QC 2.1.11	Procalcitonin Control	15.00 €/vial	immediately
QC 2.1.12	Calprotectin-Elastase Control	28.00 €/vial	immediately
QC 2.1.13	SARS-CoV-2 IgG/IgM Serum Control	25.00 €/vial	immediately
QC 2.1.14	CRP Control	20.00 €/vial	immediately
QC 2.2.10	Faecal Diagnostic – Faecal Occult Blood Control	20.00 €/vial	immediately
QC 2.2.11	Autoimmunity – Antiphospholipidsyndrome	15.00 €/vial	immediately

Data sheets for each product are available on request.

* Minimum purchase: 1 batch of 500 vials



4 Fertility & Pregnancy

Product Number	Product Name	Pricing	Availability
FPPA 4.7.1.1	Normal Pregnancy Panel	220.00 €/panel	immediately
FPPA 4.7.2.1	Normal Pregnancy Panel – Consecutive Donations	220.00 €/panel	immediately
FPPA 4.7.8.1	Pregnancy Panel – Associated Diseases - Serum	220.00 €/panel	immediately
FPPA 4.7.8.2	Pregnancy Panel – Associated Diseases - Plasma	220.00 €/panel	immediately
FPPA 4.7.9.1	Total β-hCG Panel	220.00 €/panel	immediately
FPPA 4.7.9.2	DHEA-S Panel	220.00 €/panel	immediately
FPPA 4.7.9.3	Progesteron Panel	220.00 €/panel	immediately
PRCO 4.9.1.1.1	Oestrogen Collective	2,000.00 €/collective	immediately

Each panel consists of 10 samples (volume per sample: 1.0 ml, different volumes on request).

Data sheets for each product are available on request.



5 Human Bio-Materials – Disease State

Product Number	Product Name	Pricing	Availability
Oncology Products			
DSPA 4.1.7.1.2	Cancer-Antigen 19-9 (CA 19-9) Panel	450.00 €/panel	immediately
DSPA 4.1.7.1.3	Cancer-Antigen 125 (CA 125) Panel	450.00 €/panel	immediately
DSPA 4.1.7.1.4	Carcino Embryonic Antigen (CEA) Panel	450.00 €/panel	immediately
DSPA 4.1.7.1.5	Prostate Specific Antigen (PSA) Panel	450.00 €/panel	immediately
DRCO 4.9.1.1.2	Tumor Collective	1,000.00 €/collective	immediately
Autoimmunity Products			
DSPA 4.1.1.1.9	Antiphospholipidsyndrome (APS) Panel	220.00 €/panel	immediately
DSPA 4.1.1.1.2	Rheumatoid Factor Panel of Rheumatoid Arthritis	250.00 €/panel	immediately
DSPA 4.1.1.2.2	Rheumatoid Arthritis Panel	250.00 €/panel	immediately
DSPA 4.1.1.2.10	Systemic Lupus Erythematosus Panel	250.00 €/panel	immediately
DSPA 4.1.1.2.11	Sjögren Syndrome Panel	250.00 €/panel	immediately
DSPA 4.1.1.1.12	Crohn's Disease Panel	350.00 €/panel	immediately
DSPA 4.1.1.2.13	Ulcerative Colitis Panel	250.00 €/panel	immediately
DSBU 4.1.1.1.1	Rheumatoid Arthritis Bulk	2,400.00 €/bulk	immediately
DSBU 4.1.1.1.3	ANA Bulk	2,400.00 €/bulk	immediately
DSBU 4.1.1.1.4	Myasthenia gravis Bulk	2,400.00 €/bulk	immediately
DSBU 4.1.1.1.5	Systemic Lupus Erythematosus Bulk	2,400.00 €/bulk	immediately
DSPO 4.1.1.1.1	Rheumatoid Arthritis Pool 1.0l	12,000.00 €/l	immediately

Each panel consists of 10 samples (volume per sample: 1.0 ml, different volumes on request).

Each bulk consists of ~ 200.00 ml. Data sheets for each product are available on request.

Product Number	Product Name	Pricing	Availability
Diabetes Products			
DSPA 4.1.3.1.4	Glutamate-Decarboxylase Antibodies (GADA) Panel	200.00 €/panel	immediately
DSPA 4.1.3.3.1	Diabetes Type I & II Panel	200.00 €/panel	immediately
DSPA 4.1.3.2.1	Diabetes Type I Panel	200.00 €/panel	immediately
DSPA 4.1.3.2.2	Diabetes Type II Panel	200.00 €/panel	immediately
DSBU 4.1.3.2.1	Diabetes Type I Bulk	2,200.00 €/bulk	immediately
DSBU 4.1.3.2.2	Diabetes Type II Bulk	2,200.00 €/bulk	immediately
Infectious Diseases Products			
DSPA 4.1.4.1.1	Cytomegalovirus IgG positive Panel	750.00 €/panel	immediately
DSPA 4.1.4.1.3	EBV Capsid-Antigen IgG positive Panel	750.00 €/panel	immediately
DSPA 4.1.4.1.5	HBs Antigen positive Panel	250.00 €/panel	immediately
DSPA 4.1.4.1.6	HBV IgG positive Panel	750.00 €/panel	immediately
DSPA 4.1.4.1.7	Hepatitis C Virus IgG positive Panel	750.00 €/panel	immediately
DSPA 4.1.4.1.16	Mycoplasma pneumoniae IgG positive Panel	750.00 €/panel	immediately
DSPA 4.1.4.1.17	H. Influenzae IgG positive Panel	750.00 €/panel	immediately
DSPA 4.1.4.1.18	Influenza A IgG positive Panel	750.00 €/panel	immediately
DSPA 4.1.4.1.19	Influenza B IgG positive Panel	750.00 €/panel	immediately
DSPA 4.1.4.1.20	RSV IgG positive Panel	750.00 €/panel	immediately
DSPA 4.1.4.1.21	Adenovirus IgG positive Panel	750.00 €/panel	immediately
DSPA 4.1.4.1.22	Herpes Simplex 1+2 IgG positive Panel	750.00 €/panel	immediately
DSPA 4.1.4.1.23	Mumps Virus IgG positive Panel	750.00 €/panel	immediately
DSPA 4.1.4.1.24	Parainfluenza 1+2+3 IgG positive Panel	750.00 €/panel	immediately
DSPA 4.1.4.1.25	Parvovirus B19 IgG positive Panel	750.00 €/panel	immediately
DSPA 4.1.4.1.26	Varicella Zoster IgG positive Panel	750.00 €/panel	immediately
DSPA 4.1.4.1.27	Enterovirus IgG positive Panel	750.00 €/panel	immediately
DSPA 4.1.4.1.28	Measles Virus IgG positive Panel	750.00 €/panel	immediately
DSPA 4.1.4.1.33	Chlamydia pneumoniae IgG positive Panel	750.00 €/panel	immediately
DSPA 4.1.4.1.34	Borrelia IgG positive Panel	750.00 €/panel	immediately
DSBU 4.1.4.2.19	Hepatitis C Virus IgG Bulk	6,000.00 €/bulk	immediately
DSBU 4.1.4.2.59	Influenza A IgG Bulk	6,000.00 €/bulk	immediately
DSPO 4.1.7.1.1	Toxoplasma gondii IgM Pool 1.0 l	8,000.00 €/l	immediately
Sepsis Products			
DSPA 4.1.5.7.1	Sepsis Panel	2,500.00 €/panel	immediately
DSPA 4.1.5.7.2	CRP Panel	300.00 €/panel	immediately
DSPA 4.1.5.7.3	PCT Panel	200.00 €/panel	immediately
DSBU 4.1.5.1.1	CRP Bulk	1,400.00 €/bulk	immediately
DSPO 4.1.5.1.1	PCT Pool 1.0 l	7,000.00 €/l	immediately
DSPO 4.1.5.1.2	CRP Pool 1.0 l	7,000.00 €/l	immediately

Each panel consists of 10 samples (volume per sample: 1.0 ml, different volumes on request).

Each bulk consists of ~ 200.00 ml. Data sheets for each product are available on request.

Product Number	Product Name	Pricing	Availability
SARS-CoV-2 Products			
DSPA 4.1.9.1.2	SARS-CoV-2 Distinction Panel	6,000.00 €/panel	immediately
DSPA 4.1.9.4.1	SARS-CoV-2 negative Panel	300.00 €/panel	immediately
DSPA 4.1.9.5.1	Analytical Specificity Panel for SARS-CoV-2	6,000.00 €/panel	immediately
DSPA 4.1.9.6.1	Normal SARS-CoV-2 negative Panel	2,020.00 €/panel	immediately
DSPA 4.1.9.8.1	SARS-CoV-2 Validation Panel	4,500.00 €/panel	immediately
DSPA 4.1.9.11.1	SARS-CoV-2 negative measured Plasma Panel	600.00 €/panel	immediately
DSPA 4.1.9.12.1	SARS-CoV-2 positive Plasma Panel	800.00 €/panel	immediately

Data sheets for each product are available on request.

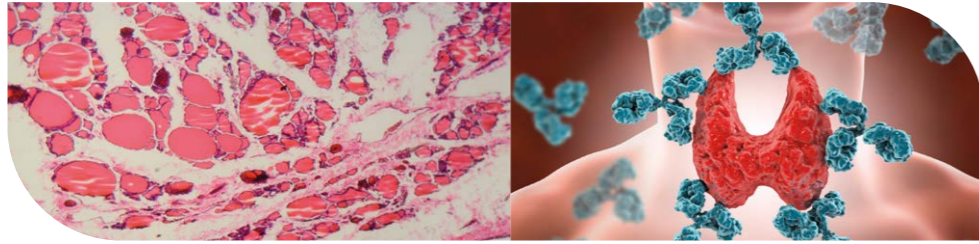
Product Number	Product Name	Pricing	Availability
DSPA 4.1.9.13.1	SARS-CoV-2 negative Serum Panel	300.00 €/panel	immediately
DSPA 4.1.9.14.1	Common Coronavirus Single Panel – HKU1	2,400.00 €/panel	immediately
DSBU 4.1.9.10.1.1	SARS-CoV-2 positive Serum Bulk	7,000.00 €/bulk	immediately
DSBU 4.1.9.10.2.1	SARS-CoV-2 positive Plasma Bulk	6,000.00 €/bulk	immediately
DSPA 4.1.9.10.1	Serum & Plasma Quartet of SARS-CoV-2 recovered Donors	460.00 €/quartet	immediately
DSPO 4.1.9.1.1	SARS-CoV-2 Pool 1.0 l	20,000.00 €/l	immediately

Data sheets for each product are available on request.

Product Number	Product Name	Pricing	Availability
CDT Products			
DSPA 4.1.2.1.1	CDT Panel	200.00 €/panel	immediately
DSPO 4.2.1.1.2	CDT Pool 100 ml	900.00 €/pool	immediately
Allergy total & specific IgE Products			
ALPA 4.1.7.1.1	Allergy Panel – Total IgE	180.00 €/panel	immediately
ALPA 4.1.7.3.1	Allergy Panel – Specific IgE	180.00 €/panel	immediately
ALPA 4.1.7.3.1.1	Allergy Panel – Cat IgE (e1)	180.00 €/panel	immediately
ALPA 4.1.7.3.1.2	Allergy Panel – Dog IgE (e2)	180.00 €/panel	immediately
ALPA 4.1.7.3.1.3	Allergy Panel – Birch IgE (t3)	180.00 €/panel	immediately
ALPA 4.1.7.3.1.4	Allergy Panel – Mugwort IgE (w6)	180.00 €/panel	immediately
ALBU 4.1.7.4.1-54	Allergy Bulk – Specific IgE	1,400.00 €/bulk	immediately
ALBU 4.1.7.2.1	Allergy Bulk – Total IgE	1,400.00 €/bulk	immediately
ALPO 4.1.7.1.1	Allergy Pool – Specific IgE 1.0 l	8,000.00 €/l	immediately
Hepatology Products			
PRCO 4.9.1.1.2	Fatty Liver Collective	2,000.00 €/collective	immediately
Thyroid Diseases Products			
DRCO 4.9.1.1.1	Thyroid Collective	1,400.00 €/collective	immediately
DSPA 4.1.6.1	anti-Thyroglobulin Panel	350.00 €	immediately
DSPA 4.1.6.2	anti-Thyroidperoxidase Panel	350.00 €	immediately
DSPA 4.1.6.3	anti-TSH receptor Panel	350.00 €	immediately
DSPA 4.1.6.4	TSH Panel	350.00 €	immediately
DSPA 4.1.6.5	FT3 Panel	350.00 €	immediately
DSPA 4.1.6.6	FT4 Panel	350.00 €	immediately
DSPA 4.1.6.7	Thyroglobulin free Panel	350.00 €	immediately
DSPA 4.1.6.3.1	Hashimoto's Thyroiditis Panel	350.00 €	immediately
DSPA 4.1.6.3.2	Hyperthyroidism Panel	350.00 €	immediately
DSPA 4.1.6.3.3	Hypothyroidism Panel	350.00 €	immediately
DSPA 4.1.6.3.4	Struma Panel	350.00 €	immediately
DSPA 4.1.6.3.5	Thyroid Cancer Panel	350.00 €	immediately
DSPA 4.1.6.3.6	Thyroid Nodules Panel	350.00 €	immediately
DSPA 4.1.6.3.7	Graves' Disease Panel	350.00 €	immediately
DSBU 4.1.6.1.1	anti-TPO Bulk	2,400.00 €	immediately
DSBU 4.1.6.1.2	Graves' Disease Bulk	2,400.00 €	immediately
DSBU 4.1.6.1.3	Thyroidectomy Bulk	2,400.00 €	immediately
DSBU 4.1.6.1.4	anti-Tg Bulk	2,400.00 €	immediately
DSBU 4.1.6.1.5	anti-TSH receptor (TRAb) Bulk	2,400.00 €	immediately
DSPO 4.1.6.4.3	anti-Thyroidperoxidase Antibodies (a-TPO) Pool 5.0 l	6,500.00 €/l	immediately
DSPO 4.1.6.4.4	anti-Thyroglobulin Antibodies (a-Tg) Pool 5.0 l	6,200.00 €/l	immediately
DSPO 4.1.6.4.5	anti-TSH receptor (TRAb) Pool 5.0 l	7,000.00 €/l	immediately

Each panel consists of 10 samples (volume per sample: 1.0 ml, different volumes on request).

Each bulk consists of ~ 200.00 ml. Data sheets for each product are available on request.



6 Human Tissues & Specialities

Product Number	Product Name	Pricing	Availability
Human Tissues			
HTT 5.1.1	Thyroid Tissue – small undefined samples without viral testing, fresh frozen	50.00 €/g	immediately
HTT 5.1.2	Thyroid Tissue – small undefined samples with viral testing, fresh frozen	25.00 €/g	immediately
Human Proteins			
PCHP 3.2.10	hp Thyroid Peroxidase (TPO)	1,970.00 €/mg	immediately
Faecal Samples			
SFS 5.1.1	Pancreatic Elastase	35.00 €/sample	immediately
SFS 5.1.2	Normal Donors	30.00 €/sample	immediately

Data sheets for each product are available on request.

Prospective Collections

Prospective small volume Samples

Samples of	Pricing	Availability
Tumor markers: other than off the shelf products	on demand	3-6 months
Procalcitonin	on demand	2-3 months
Allergy (10 samples of each 1.0 ml with e.g. e1, e2, i1, i3, g1, g6, t3, t4, t7, w1, w6)*	on demand	3-6 months
Alpha-Fetoprotein Collection: 20 Samples of each 3 Level Ranges (total amount: 60 samples)	on demand	6 months

* Individual Donations on request.

Prospective large volume Bulks & Pools

Bulks & Pools	Pricing	Availability
Diabetes Bulk	on demand	2-3 months
Rheumatoid Factor Bulk (3 l)	on demand	3 months
CRP (c-reactive protein) Bulk	on demand	2-3 months
Thyroid Disease Bulk (e.g. low-titered TRAK, a-TPO)	on demand	2-3 months
Allergy Bulk (e.g. Polls, Animals, Food)	on demand	2-3 months
Normal Human Serum 50 l each Batch	on demand	3 months
Normal Human Serum 100 l each Batch	on demand	5 months
Single Donations 10-20 l (Serum or Plasma of self-declared healthy Donors)	on demand	2 months
Single Donations 50 l (Serum or Plasma of self-declared healthy Donors)	on demand	5 months

Please also ask for pools.

Study Site – Customised Sample Procurement

Volumes:

- small and large volume samples

Every matrix and all anti-coagulants possible:

- whole blood
- serum (off-the-clot or induced clotting)
- plasma (centrifuged or apheresis)
- erythrocytes concentrate
- swabs
- urine and faeces

Address donors in a targeted manner, e.g. for:

- pre-analytic specifications
- matched sets
- consecutive donations

We offer processing and specifications according to customer's requirements.



Human Bio-Materials



made in germany



EUROPÄISCHE UNION

Europäischer Fonds für
Regionale Entwicklung