

Product Catalogue

Human matrix based Controls and Calibrators

Version 11/17

CONTROL SERA & CALIBRATORS OF THE HIGHEST QUALITY

High quality is the final result of ambitious goals, expert knowledge, optimized processes and precise execution. Safety, quality and continuous improvement are the top priorities for all **DiaServe** employees. This is how we work together to fulfil requirements, satisfy our clients and maintain long-lasting customer relations. Ours is a mindset that **DiaServe** clients have valued for over 15 years, because it makes us a reliable partner of customised human control sera and calibrators.”

Moreover, services or products we offer range from human blood and urine samples to fully processed and freeze-dried human based products.

How we work:

- Careful selection and qualification of suppliers
- Raw materials qualification and incoming testing
- Fully internal ownership of the manufacturing steps
- Close collaboration with renowned institutes and leading suppliers
- Internal processes managed by highly expert staff
- The highest batch-to-batch quality and consistency
- ISO 13485 certification

OUR GUIDING PRINCIPLE:

DIRECT CONTACT WITH YOU

WITH US, YOUR PROJECT IS IN SAFE HANDS

DiaServe laboratories is one of Europe’s leading suppliers of customized IVD calibrators and controls based on human sera. In constant cooperation with renowned institutes, we use the most up-to-date research findings to continuously further develop our products and services.

Due to our vast experience in the development of EQA testing materials and the manufacturing of controls and calibrators, we are well positioned to meet the needs and demands of the market at any time. This is the reason why some of our long-term clients include EQA organisations and many market leaders in the diagnostics industry.

With us, you will know that you are in expert and safe hands. Our highly qualified team will be in close contact with you from the product specifications definition, during the pilot phase to the batch production process, to meet your specific client expectations.

Together we will find the best solution – Just try us now!



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Negative Human Products

Hu. Whole Blood (HWB)	Human Plasma	Normal hu. Serum, OTC (NHS)	Processed hu. Plasma
HWB-CPD	Plasma-CPD	NHS Single Donor	HP, Defibrinated
HWB-EDTA	Plasma-EDTA	NHS Pool	HP, Defib., Delipidized
HWB-HbA1c	Plasma-Citrate		HP, Charcoal treated
HWB-Heparin	Plasma-Heparin		HP, T3/T4-free
Erythrocytes Conc. (RBC)			HP, Steroid-free

Product description

Negative Human Products are liquid frozen material based on voluntary human blood donations. Materials are intended to support the Industries to manufacture their own Calibrators and Controls. All listed products are recruited, selected and processed according to customer's specific request.

Product features

- blood groups and genders are available on request
- products from European donors
- development and production of the processed material fits with your specific protocols
- processed human product are available also as sterile filtered units

Biohazard

The used human blood donations of European origin are tested by CE-marked kits and are non-reactive for HBsAg, anti-HIV 1/2 and anti HCV. In addition HCV and HIV are tested by PCR.

Volumes

10 ml are available for customer evaluation. Products are packed, sold in 500 ml and 2 liters seize or as single unit donation. Batches size ranges from minimum 1 package to 250 liters.

Development support:

Each unit is tested and characterized according to specific customer specifications. Our R&D and Production experts have been trained to develop the product with you and according your specific needs. Pilot lots are manufactured at our facilities, sent to your R&D units for further testing. A dedicated Project Leader is assigned to each project and progresses are jointly monitored and tracked to completion.

Order Information

1120	HWB-CPD
1123-1	HWB-EDTA
1121	HWB-HbA1c
1122	HWB-Heparin
1136-01	RBC
1208	H. Plasma-CPD
1216	H. Plasma-EDTA
1108	H. Plasma-Citrate
1123	H. Plasma-Heparin
1001	NHS Single Donations
1020	NHS Pool
1009	HP, Defibrinated
1011	HP, Defib., Delipidiezd
1030	HP, Charcoal treated
1014	HP, T3/T4-free
1016	HP, Steroid-free

Disease State Plasma

We provide bulk disease state plasma units, specialising in infectious diseases, autoimmunity and allergy. Our human disease state plasma units are collected, screened, processed, stored and shipped based on ethical considerations and customers' specific requirements. We test our plasma for specific markers of interest and are able to offer immunological and molecular characterisation data along with demographic information. Our extensive supply chain of European blood banks, hospitals and donor centres enable us to screen for rare diseases and process materials to specific testing requirements.

TORCH	Hepatitis	Virology	Infectious Diseases
Toxoplasmosis	HAV	Parvovirus	Chlamydia Trachomatis
Varicella-Zoster	HBc	EBV	Chlamydia Pneumoniae.
CMV	HBe	HIV-1	H. Pylori
Rubella	HCV	HIV-2	Borellia burdorferi
HSV 1	HBsAg, ad	HTLV I	Syphilis
HSV 2	HBsAg, ay	HTLV II	M. Tuberculosis
HSV 1,2	HBcAg	Mumps	Chagas
	HBeAg	WNV	

Autoimmunity (connective tissue)	Autoimmunity (cardiolipin, vasculitis)	Autoimmunity (Thyroid, Celiac, ...)	Allergy
ENA and ANA	Cardiolipin IgA,IgG,IgM	Anti-TPO	Mite
A-CCP	β2-Glycoprotein IgA,G,M	Anti TG	Foods
RF (sub-classes)	GBM antibodies	LKM1 antibodies	Grass
SS-A/ro	MPO antibodies	Anti-Kell	Animal
SS-B/la	PR3 antibodies	Gliadin DP IgA	
Scl-70		Gliadin DP IgG	Components
dsDNA and ssDNA			

Product description

Human products are frozen liquid materials based on voluntary human blood donations. Materials are intended to support the Industries to manufacture their own Calibrators and Controls. All listed products are selected and processed according to customer's specific request.

Biohazard

Each disease state unit is tested by CE-marked or by FDA approved kits and is non-reactive for HBsAg, anti-HIV 1/2 and anti HCV.

Volumes

Products are packed, sold in customized volume size from a few ml to whole donation units (200-500 mL). Each batch is

sampled and pre-approved by the customer on their specific analytical systems.

Search and Reservation support:

Our Supply-chain experts have established world-wide contacts and relationships and been trained to perform searches of the disease state samples including rare diseases samples.

Selected and approved units can be reserved and stored in our facilities.

Order Information

Due to the volume of our biobank we will provide a list of on stock materials suited to your enquiry. Our mailing service keeps our customers updated on our inventory. Grid pricing is based on cumulative volumes.

MASTER Calibrators

Components:

10609 Bilirubin	10607 Lipids	10605 Enzymes	10601 Metabolites	10603 Electrolytes
Bilirubin, direct	Cholesterol, HDL	AST	Uric Acid	Cl
Bilirubin, total	Cholesterol, LDL	ALT	Creatinine	Na
	Cholesterol	γGT	Urea	Mg
	Triglycerides	ALP	Lactate	Ca
		CK	Glucose	Fe
		LDH	Total Proteins	P
				K
				Cu

Product description

MASTER Calibrators are lyophilised native human sera stored at – 80 °C. Only human derivate substances and proteins have been used. The concentrations of the analytes have been assigned by external certified laboratories and with 1st hierarchic reference method and/or International Reference Materials.

Product features

- human serum based
- excellent cummutability
- low optical density after reconstitution
- 6-year shelf life at -80°C

SI UNIT			
Calibration Hierarchy	1 st Calibrator	1 st Ref. MP	NMI
		2 nd Ref. MP	
	2 nd Calibrator		MFR
	Working Cal	Selected MP	
	Laboratory Cal	Standing MP	
		Routine MP	Clinical Lab.
	Routine sample		
	Patient result		

Reference Centers:

Enzymes: Laboraf (hSR, Milan)
 Bilirubin: Gent University
 Lipids: Gent University
 Metabolites: Gent University
 Electrolytes: INSTAND e.V.

Volume: 2.0 ml

Storage and Stabilities

Lyophilized: 2 year at -20 °C
 6 year at -80 °C

After reconst.: 1 day at +18/25°C
 7 days at +2/8°C
 1 month at –20°C

(Refer to packaging insert for exceptions.
 i.e. Bilirubin)

Biohazard

The used human blood donations of European origin are tested by CE-marked kits and are non-reactive for HBsAg, Anti-HIV 1/2 and Anti-HCV. In addition HCV and HIV are tested by PCR.

Order Information

10609 MASTER Calibrator Bilirubin
 10607 MASTER Calibrator Lipids
 10605 MASTER Calibrator Enzymes
 10601 MASTER Calibrator Metabolites
 10603 MASTER Calibrator Electrolytes

VERIFY Panels

10610 <u>Bilirubin</u>	10608 <u>Lipids</u>	10606 <u>Enzymes</u>	10602 <u>Metabolites</u>	10604 <u>Electrolytes</u>
Bilirubin, direct	Cholesterol, HDL	AST	Uric Acid	Cl
Bilirubin, total	Cholesterol, LDL	ALT	Creatinine	Na
	Cholesterol	γGT	Urea	Mg
	Triglycerides	ALP	Lactate	Ca
		CK	Glucose	Fe
		LDH	Total Proteins	Phos
				K
				Cu

Product description

VERIFY Panels are each a set of 5 liquid native human sera without preservatives and stored at – 80 °C. Only human derivate substances and proteins have been used. The concentrations of the analytes have been assigned by external certified laboratories and with 1st hierarchic reference method and/or International Reference Materials.

Product Use

SI UNIT			
Calibration Hierarchy	1 st Calibrator	1 st Ref. MP	NMI
	2 nd Calibrator	2 nd Ref. MP	
	Working Cal	Selected MP	MFR
	Commercial Cal	Standing MP	
	Routine sample	Routine MP	Clinical Lab.
	Patient result		

The VERIFY Panel are intended to measure the quality of the manufacturer’s target values assignment protocol and outputs

Volume: 2.0 ml x 5 levels

Product features

- traceability to Ref. Materials and methods
- commutability with patient’s samples
- 5 analytes concentrations covering the relevant analytical measuring range

Biohazard

The used human blood donations of European origin are tested by CE-marked kits and are non-reactive for HBsAg, Anti-HIV 1/2 and Anti-HCV. In addition HCV and HIV are tested by PCR.

Reference Centers:

Enzymes: Laboraf (hSR, Milan)
 Bilirubin: Gent University
 Lipids: Gent University
 Metabolites: Gent University
 Electrolytes: INSTAND e.V.

Storage and Stabilities

After opening: 1 year at -20 °C
 After thawing: 1 day at +18/25°C
 1 week at +2/8°C
 1 month at –20°C
 (Refer to packaging insert for exceptions. i.e. Bilirubin)

Order Information

- 10610 VERIFY Panel Bilirubin
- 10608 VERIFY Panel Lipids
- 10606 VERIFY Panel Enzymes
- 10602 VERIFY Panel Metabolites
- 10604 VERIFY Panel Electrolytes

Chemistry Controls - I

Components:

Acid Phosphatase, non prostatic	Cholesterol	Lipase
Acid Phosphatase, total	Cholesterol, HDL	Lithium
Albumin	Cholesterol, LDL	Magnesium
Alkaline Phosphatase	Creatine-Kinase	Phosphorous
Alanin-Aminotransferase	Creatine-Kinase MB	Potassium
Amylase, total	Copper	Protein, total
Amylase, pancreatic	Creatinine	Sodium
Aspartat-Aminotransferase	γ -Glutamyl-Transferase	Triglycerides
Bilirubin, total	Glucose	Urea
Bilirubin, direct	α -Hydroxyburat-Dehydrogenase	Uric Acid
Calcium	Iron	Zinc
Chloride	Lactate	

Product description

Chemistry Controls-I are lyophilized control materials based on human serum. List of the analytes has been designed to meet the requirements of bench-top analysers. The concentrations of the analytes are adjusted with various pure chemicals and preparations from animal and human tissues.

Product features

- basic chemistry controls, dedicated to small clinical chemistry analysers
- human serum based
- excellent cummutability
- 3-year shelf life at 2-8°C

Biohazard

The used human blood donations of European origin are tested by CE-marked kits and are non-reactive for HBsAg, Anti-HIV 1/2 and Anti-HCV. In addition HCV and HIV are tested by PCR.

Analytes: 35 qualified analytes

Volumes: 3.0 ml
5.0 ml

Storage and Stabilities

Lyophilized: 3 years at +2/8°C
After reconst.: 1 day at +18/25°C
7 days at +2/8°C
6 months at -20°C

(Refer to packaging insert for exceptions)

Order Information

[10140 Chemistry Controls I](#)

Chemistry Controls - II

Components:

Acetaminophen	Cholinesterase	Lithium
Acid Phosphatase, non prostatic	Copper	Magnesium
Acid Phosphatase, total	Cortisol	D/L-Phenylalanine
Alanine-Aminotransferase	Creatine-Kinase	Phenytoin
Albumin	Creatine-Kinase MB	Phospholipids
Aldolase	Creatinin	Phosphorous
Alkaline Phosphatase	Digoxin	Potassium
Amylase, pancreas	Gentamycin	Protein, total
Amylase, total	Glucose	Salicylat
Apolipoprotein A1	Glutamatdehydrogenase	Sodium
Apolipoprotein B	γ -Glutamyltransferase	T3
Aspartate-Aminotransferase	hu. Thyroid stimulating Hormone	T3, free
Bile Acid	α -Hydroxybutyrate-Dehydrogenase	T4
Bilirubin, direct	Hydroxybutyric Acid	T4, free
Bilirubin, total	Immunoglobulin A	Teophyllin
Blood urea nitrogen	Immunoglobulin G	Tombramycin
Calcium	Immunoglobulin M	Transferrin
Carbamacepine	Iron	Triglycerides
Chloride	Lactate	Urea
Cholesterol	Lactate Dehydrogenase	Uric Acid
Cholesterol, HDL	Leucine-Aminopectidase	Zinc
Cholesterol, LDL	Lipase	

Product description

Chemistry Controls-II are lyophilized control materials based on human serum.

List of the analytes has been designed to meet the requirements of medium and large clinical chemistry analysers.

The concentrations of the analytes are adjusted with various pure chemicals and preparations from animal and human tissues.

Product features

- chemistry controls dedicated to the medium/large clinical chemistry analysers
- human serum based
- human recombinant enzymes:
 - CKMM and CKMB
 - Pancreatic Lipase
- excellent cummutability
- 3-year shelf life at 2-8°C



Biohazard

The used human blood donations of European origin are tested by CE-marked kits and are non-reactive for HBsAg, Anti-HIV 1/2 and Anti-HCV. In addition HCV and HIV are tested by PCR.

Analytes: 65 qualified analytes

Volumes: 3.0 ml
5.0 ml

Storage and Stabilities

Lyophilized: 3 years at +2/8°C
After reconst.: 1 day at +18/25°C
7 days at +2/8°C
6 months at -20°C

(Refer to packaging insert for exceptions)

Order Information

10140 Chemistry Controls II

Chemistry Controls -III

Components:

Acetaminophen	C-reactive protein	Phenylalanin
Acid Phosphatase, non prostatic	Creatine-Kinase	Phenytoin
Acid Phosphatase, total	Creatine-Kinase MB	Phospholipids
Alanin-Aminotransferase	Creatinine	Phosphorous
Albumin	Digitoxin	Potassium
Alkaline Phosphatase	Digoxin	Primidone
Amylase, pancreas	Ferritin	Protein, total
Amylase, total	Gentamycin	Rheumatoid Factor
<i>Anti-streptolysin O</i>	Glucose	Salicylate
Apolipoprotein A1	Glutamate-Dehydrogenase	Sodium
Apolipoprotein B	γ -Glutamyltransferase	T3, free
Aspartat-Aminotransferase	human Thyroid Stimulating Hormone	T3, uptake
Bicarbonate	Hydroxybutyric Acid	T4, free
Bile Acid	α -Hydroxyburate-Dehydrogenase	Teophyllin
Bilirubin, direct	Immunoglobulin A	Tombramycin
Bilirubin, total	Immunoglobulin E	Transferrin
Calcium	Immunoglobulin G	Triglycerides
Carbamacepine	Immunoglobulin M	UIBC
Chloride	Iron	Urea
Cholesterol	Lactate	Uric Acid
Cholesterol, HDL	Lactate Dehydrogenase	Valproic Acid
Cholesterol, LDL	Lipase	Vancomycin
Cholinesterase	Lithium	Zinc
Copper	Magnesium	
	Phenobarbital	

Product description

Chemistry Controls-III are lyophilized control materials based on human serum. List of the analytes has been designed to meet the requirements of large automated biochemistry laboratories.

The concentrations of the analytes are adjusted with various pure chemicals and preparations from animal and human tissues.

Product features

- consolidated products dedicated to high-throughput work-flow cells
- human serum based
- human recombinant enzymes:
 - CKMM and CKMB
 - Pancreatic Lipase
- excellent cummutability
- 3-year shelf life at 2-8°C



Biohazard

The used human blood donations of European origin are tested by CE-marked kits and are non-reactive for HBsAg, Anti-HIV 1/2 and Anti-HCV. In addition HCV and HIV are tested by PCR.

Analytes: 72 qualified analytes

Volumes: 3.0 ml
5.0 ml

Storage and Stabilities

Lyophilized: 3 years at +2/8°C
After reconst.: 1 day at +18/25°C
7 days at +2/8°C
6 months at -20°C

(Refer to packaging insert for exceptions)

Order Information

10140 Chemistry Controls-III

Chemistry Calibrator

Components:

Acid Phosphatase, prostatic	Cholesterol	Lactate-Dehydrogenase
Acid Phosphatase, total	Cholesterol, LDL	Lipase
Alanine-Aminotransferase	Cholesterol, HDL	Lithium
Albumin	Cholinesterase	Magnesium
Alkaline Phosphatase	Copper	Phosphorous
Amylase, pancreas	Creatine-Kinase	Potassium
Amylase, total	Creatinine	Protein, total
Aspartate-Aminotransferase	Glucose	Sodium
Bilirubin, direct	Glutamate-Dehydrogenase	Triglycerides
Bilirubin, total	γ -Glutamyltransferase	Urea
Calcium	Iron	Uric Acid
Chloride	Lactate	Zinc

Product description

The Chemistry Calibrator is a lyophilized calibrator based on human serum. Design is carried out according to our customers' specification. The concentrations of the analytes are adjusted with various pure chemicals and preparations from animal and human tissues.

Product features

- human serum based
- excellent commutability
- system approved calibrator values
- low optical density after reconstitution
- 3-year shelf life at 2-8°C

Biohazard

The used human blood donations of European origin are tested by CE-marked kits and are non-reactive for HBsAg, Anti-HIV 1/2 and Anti-HCV. In addition HCV and HIV are tested by PCR.

Analytes: 36 qualified analytes

Volume: 3.0 ml

Storage and Stabilities

Lyophilized: 3 years at +2/8°C

After reconst.: 1 day at +18/25°C

1 week at +2/8°C

6 months at -20°C

(Refer to packaging insert for exceptions)

Order Information

10140-00 Chemistry Calibrator

Lipid Controls/Calibrator

Components:

ApolipoproteinA1	Homocystein
Apolipoprotein B	Phospholipids
Cholesterol-total	Triglycerides
Cholesterol, HDL	Lipoprotein (a)
Cholesterol, LDL	NEFA

Product description

Lipid Controls/calibrators are lyophilized materials based on human serum. Designs are carried out according to our customers` specifications. The concentrations of the analytes are adjusted by adding human plasma fractions.

Product features

- human serum based
- excellent commutability
- comprehensive controls for lipids / lipoproteins
- 2 weeks open-vial stability (2-8°C) after reconstitution

Biohazard

The used human blood donations of European origin are tested by CE-marked kits and are non-reactive for HBsAg, Anti-HIV 1/2 and Anti-HCV. In addition HCV and HIV are tested by PCR.

Analytes: 10 qualified analytes

Volume: 2.0 ml

Storage and Stabilities

Lyophilized: 3 years at +2/8°C

After reconst.: 1 day at +18/25°C

2 weeks at +2/8°C

1 month at -20°C

(Refer to packaging insert for exceptions)

Order Information

10112 Lipid Controls/ Calibrator

Cardiac Marker Controls

Components:

B-type natriuretic peptide	C-reactive Protein
NT-pro-BNP	Homocystein
Copeptin	Myoglobin
Creatine-Kinase	Troponin I
Creatine-Kinase MB	Troponin T
Digoxin	

Product description

Cardiac Marker Controls are lyophilized control materials based on human serum. Designs are carried out according to our customers` specifications. The concentrations of the analytes are adjusted with preparations from recombinant proteins and human tissue.

Product features

- comprehensive cardiac marker controls
- human serum based
- excellent commutability
- method- and system specific assigned values
- Product is available also as Immunology endocrinology control in combination with
 - Vitamines
 - Hormones
 - Tumor markers



Biohazard

The used human blood donations of European origin are tested by CE-marked kits and are non-reactive for HBsAg, Anti-HIV 1/2 and Anti-HCV. In addition HCV and HIV are tested by PCR.

Analytes: 11 qualified analytes

Volume: 2.0 ml

Storage and Stabilities

Lyophilized: 2 years at +2/8°C
 After reconst.: 1 day at +18/25°C
 2 days at +2/8°C
 1 month at -20°C
 (Refer to packaging insert for exceptions)

Order Information

10101 Cardiac Marker Controls

Bilirubin Controls

Components:

Bilirubin, conjugated
Bilirubin, unconjugated

Product description

Bilirubin Controls are lyophilized materials based on human serum. Levels are especially designed for neonatal controls.

Product features

- excellent stability after reconstitution
- 2-year shelf life at +2/8 °C
- 3-year at -20 °C

Biohazard

The used human blood donations of European origin are tested by CE-marked kits and are non-reactive for HBsAg, Anti-HIV 1/2 and Anti-HCV. In addition HCV and HIV are tested by PCR.

Volume: 2.0 ml

Storage and Stabilities

Lyophilized: 2 years at +2/8°C

After reconst.: 1 day at +18/25°C

1 week at +2/8°C

1 month at -20°C

(Refer to packaging insert for exceptions)

Order Information

10122 Bilirubin Controls

Fructosamine Controls / Calibrator

Components:

Fructosamine

Product description

The Fructosamine Controls/Calibrator is a material based on human serum. Design is carried out according to our customers' specification.

Product features

- excellent stability after reconstitution
- excellent commutability due to glycated Albumin
- low optical density after reconstitution
- 2-year shelf life at 2-8°C

Biohazard

The used human blood donations of European origin are tested by CE-marked kits and are non-reactive for HBsAg, Anti-HIV 1/2 and Anti-HCV. In addition HCV and HIV are tested by PCR.

Volumes: 1.0 ml
2.0 ml

Storage and Stabilities

Lyophilized: 2 years at +2/8°C
After reconst.: 1 day at +18/25°C
1 week at +2/8°C
1 month at -20°C

Order Information

10143 Fructosamine Control
10143-00 Fructosamine Calibrator



Protein Controls / Calibrators

Components:

Albumin	Ceruloplasmin	Immunoglobulin E
α -1-Antitrypsin	C-Reactive Protein	Kappa Light Chains
α -1-Glycoprotein	Cystatin C	Lambda Light Chains
α -2-Macroglobulin	Ferritin	Myoglobin
β -2-Microglobulin	Haptoglobin	Prealbumin
Anti Streptolysin O	Hemopexin	Rheumatoid Factor
Antithrombin III	Immunoglobulin A	Retinol Binding Protein
Complement Factor 3	Immunoglobulin G	Soluble Transferrin Receptor
Complement Factor 4	Immunoglobulin M	Transferrin

Product description

Protein Controls/Calibrator are liquid, ready-for-use materials, based on normal or two-fold concentrated human serum. Design is carried out according to our customers` specifications. The concentrations of the analytes are adjusted by concentration techniques and spiking of human proteins.

Product features

- liquid, ready-for-use
- excellent commutability
- comprehensive immunology / protein controls
- 2 years shelf-life at +2-8 °C

Biohazard

The used human blood donations of European origin are tested by CE-marked kits and are non-reactive for HBsAg, Anti-HIV 1/2 and Anti-HCV. In addition HCV and HIV are tested by PCR.

Analytes: 27 qualified proteins

Volume : 1.0 ml

Storage and Stabilities

Shelf-life: 2 years at +2/8°C

After opening: 1 day at +18/25°C

4 weeks at +2/8°C

6 months at -20°C

(Refer to packaging insert for exceptions)

Order Information

10106 Protein Controls

10106-00 Protein Calibrator



Electrophoresis Controls

Components:

Albumin
 α -1-Globulin
 α -2-Globulin
 β -Globulin
 β -1-Globulin
 β -2-Globulin
 γ -Globulin
 Protein, total

Product description

Electrophoresis Controls are liquid, ready-for-use control materials based on human serum. Designs are carried out according to our customers` specifications.

Product features

- liquid, ready-for-use
- excellent stabilities
- excellent commutability
- different electrophoretic patterns on request

Biohazard

The used human blood donations of European origin are tested by CE-marked kits and are non-reactive for HBsAg, Anti-HIV 1/2 and Anti-HCV. In addition HCV and HIV are tested by PCR.

Analytes: 8 qualified parameters

Volume: 1.0 ml

Storage and Stabilities

Shelf-life: 2 years at +2/8°C

After opening: 1 day at +18/25°C

1 week at +2/8°C

(Refer to packaging insert for exceptions)

Order Information

10011 Electrophoresis Controls

Hormone Controls

Components:

Adrenocorticotrophic Hormone	Follicle-stimulating Hormone	Somatotropin
Aldosterone	hu. chorionic Gonadotropin	T3
Calcitonin	Insulin	T4
Cortisol	Luteinizing Hormone	T3, free
C-Peptide	Progesterone	T4, free
DHEA Sulfate	17-OH-Progesterone	Testosterone
Estradiol	Prolactin	Testosterone, free
Folate	Parathyroid Hormone	Thyroid-stimulating Hormone
	hu. Growth Hormone	Vitamine B12

Product description

Hormone Controls are lyophilized control materials based on human serum. Designs are carried out according to our customers` specifications. The concentrations of the analytes are adjusted with steroids and proteohormones.

Analytes: 26 qualified hormones

Volumes: 3.0 ml
5.0 ml

Product features

- 1 week open vial stability (+2/8°C) after reconstitution
- excellent commutability
- comprehensive control for steroids and proteohormones
- Product is available also as Immunology endocrinology control in combination with
 - Vitamines
 - Tumor markers
 - Cardiac markers



Storage and Stabilities

Lyophilized: 3 years at +2/8°C
 After reconst.: 1 day at +18/25°C
 1 week at +2/8°C
 (Refer to packaging insert for exceptions)

Order Information

10108 Hormone Controls

Biohazard

The used human blood donations of European origin are tested by CE-marked kits and are non-reactive for HBsAg, Anti-HIV 1/2 and Anti-HCV. In addition HCV and HIV are tested by PCR.

Tumor Marker Controls

Components:

Adrenocorticotrophic Hormone	CA 27-29	hu. chorionic Gonadotropin
Aldosterone	CA 125	Ferritin
Alpha-fetoprotein	CA 72-4	Neuron specific enolase
β -2-Microglobulin	Calcitonin	Prolactin
CA 15-3	Carcinoembryonic antigen	Prostate-specific antigen , complex
CA 10-9	Cyfra 21-1	Prostate-specific antigen , free

Product description

Tumor Marker Controls are lyophilized control materials based on human serum. Designs are carried out according to our customers` specifications. The concentrations of the tumor markers are adjusted with preparations from human tissues/ fluids and cell culture materials.

Product features

- excellent commutability
- 2 week stability after reconstitution
- Product is available also as Immunology endocrinology control in combination with
 - Vitamines
 - Hormones
 - Cardiac markers



Analytes: 18 qualified analytes

Volumes

2.0 ml

Storage and Stabilities

Lyophilized: 3 years at +2/8°C

After reconst.: 1 day at +18/25°C

2 week at +2/8°C

(Refer to packaging insert for exceptions)

Order Information

10114 Tumor Marker Controls

Biohazard

The used human blood donations of European origin are tested by CE-marked kits and are non-reactive for HBsAg, Anti-HIV 1/2 and Anti-HCV. In addition HCV and HIV are tested by PCR.

TDM Controls

Components:

Acetaminophen	Estriol	Primidone
Alprazolam	Ethosuximide	Procainamide
Amikacin	Gentamicin	Propranolol Salicylate
Carbamazepine	Hydrocortisol	Streptomycin
Quinidine	Lamotrigine Lidocaine	Sultiam
Chloramphenicol	N-Acetyl-Procainamide	Tetracycline
Clobazam	Ospolot	Theophylline
Cortisol	Oxazepam	Tobramycin
Digoxin	Paracetamol	Valproic Acid
Disopyramide	Phenobarbital Phenytoin	Vancomycin


Product description

TDM Controls are lyophilized control materials based on human serum. Designs are carried out according to our customers' specifications. The concentrations of the TDMs are adjusted.

Analytes: 30 qualified drugs

Volumes: 3.0 ml
5.0 ml

Product features

- 1 week stability (+2/8°C) after reconstitution
- optically clear control material after reconstitution
- Product is available also in combination with
 - Clinical chemistry controls
 - Hormones
 - Urine control 

Storage and Stabilities

Lyophilized: 2 years at +2/8°C
 After reconst.: 1 day at +18/25°C
 1 week at +2/8°C
 1 month at -20°C
 (Refer to packaging insert for exceptions)

Order Information

[10127 TDM Controls](#)

Biohazard

The used human blood donations of European origin are tested by CE-marked kits and are non-reactive for HBsAg, Anti-HIV 1/2 and Anti-HCV. In addition HCV and HIV are tested by PCR.

Hb Controls / Calibrator


Components:

Hemoglobin

Product description

Hb Controls/Calibrator are based on human whole blood.

Hb Controls/Calibrator are available as Lyophilisate and as Liquid products.

Designs are carried out according to our customers` specifications. 

Product features

- prepared from human whole blood
- excellent commutability
- 1 week stability after opening

Biohazard

The used human blood donations of European origin are tested by CE-marked kits and are non-reactive for HBsAg, Anti-HIV 1/2 and Anti-HCV. In addition HCV and HIV are tested by PCR.

Volumes: 1.0 ml
2.0 ml

Storage and Stabilities

Shelf-life (Liquid): 6 months at +2/8°C
Shelf-life (Lyophilisate): 3 years at +2/8°C
After opening: 8 hours at +18/25°C
1 week at +2/8°C

(Refer to packaging insert for exceptions)

Order Information

10111 Hb Controls

10111-00 Hb Calibrator

HbA1c Control

Components:

HbA1c

Product description

HbA1c Controls are lyophilized control materials based on human whole blood. Designs are carried out according to our customers' specifications.

Product features

- prepared from human whole blood
- excellent commutability
- 1 week stability after opening

Biohazard

The used human blood donations of European origin are tested by CE-marked kits and are non-reactive for HBsAg, Anti-HIV 1/2 and Anti-HCV. In addition HCV and HIV are tested by PCR.

Volumes. 0.5 ml

Storage and Stabilities

Lyophilized: 2 years at +2/8°C

After reconst.: 1 day at +18/25°C

1 week at +2/8°C

(Refer to packaging insert for exceptions)

Order Information

[10123 HbA1c Controls](#)

Coagulation Controls

Components:

Activated Partial Thromboplastin Time
 Prothrombin Time
 Thrombin Time
 Fibrinogen
 Antithrombin III
 D-Dimer

Product description

Coagulation Controls are lyophilized control materials based on citrate human plasma. The coagulation factors are adjusted to normal respectively abnormal levels.

Product features

- excellent stability after reconstitution
- excellent commutability
- 2-year shelf life at +2/8°C

Biohazard

The used human blood donations of European origin are tested by CE-marked kits and are non-reactive for HBsAg, Anti-HIV 1/2 and Anti-HCV. In addition HCV and HIV are tested by PCR.

Analytes: 6 qualified analytes

Volumes: 1.0 ml
2.0 ml

Storage and Stabilities

Lyophilized: 2 years at +2/8°C

After reconst.: 1 day at +18/25°C

1 week at +2/8°C

1 month at -20°C

(Refer to packaging insert for exceptions)

Order Information

[10902 Coagulation Controls](#)

Urine Dipstick Controls

Components:

Ascorbic Acid	Nitrite
Bilirubin	Osmolality
Blood	pH
Glucose	Protein
Ketones	Pregnancy (hCG)
Leucocytes	Specific Gravity
Microalbumin	Urobilinogen

Product description

Urine Dipstick Controls are ready-for-use control materials based on human urine. Designs are carried out according to our customers` specifications. The concentrations of the analytes are adjusted with various pure chemicals.

Product features

- human urine based
- designed for dipsticks
- ready-for-use

Biohazard

The used human blood donations of European origin are tested by CE-marked kits and are non-reactive for HBsAg, Anti-HIV 1/2 and Anti-HCV. In addition HCV and HIV are tested by PCR.

Analytes: 14 qualified analytes

Volumes: 5.0 ml
10.0 ml

Storage and Stabilities

Shelf-life: 2 year at -20°C

After opening: 1 day at +18/25°C

1 week at +2/8°C

(Refer to packaging insert for exceptions)

Order Information

10920 Urine Dipstick Controls

Urine Chemistry Controls

Components:

Microalbumin	Creatinine	Phosphorus
Amylase	Glucose	Protein, total
Bilirubin	Magnesium	Sodium
Calcium	Osmolality	Urea
Chloride	Potassium	Uric Acid

Product description

Urine Chemistry Controls are lyophilized control materials based on human urine. Designs are carried out according to our customers` specifications. The concentrations of the analytes are adjusted with various pure chemicals.

Product features

- human urine based
- excellent commutability
- excellent stabilities after reconstitution

Biohazard

The donors of the used urine units have been tested by CE-marked kits and found to be non-reactive for HBsAg, Anti-HIV 1,2 and Anti-HCV. In addition HCV and HIV are tested by PCR.

Analytes: 15 qualified analytes

Volume : 5.0 ml

Storage and Stabilities

Lyophilized: 3 years at +2/8°C

After reconst.: 1 day at +18/25°C

1 week at +2/8°C

6 months at -20°C

(Refer to packaging insert for exceptions)

Order Information

10120 Urine Chemistry Controls

Third Party Manufacturer

Custom Product Development & Manufacturing

We offer a specialized custom product development and manufacturing service for tailor made in-vitro diagnostics. We collaborate with customers to determine project goals, specifications and intended product use. This interaction ensures that the developed product is suitable for the intended application. Our service also includes processing according to customer supplied methods and protocols. Our trained and experienced staff work with our customers from the selection of raw materials, custom processing and formulation to the determination of quality control requirements and acceptance criteria for product analysis, stability and inspection. Thanks to our quality management system we can ensure product integrity and consistency on a lot-to-lot basis and product reproducibility is ensured through established procedures. We guarantee confidentiality of all customer communications, procedures, processes and all other relevant information.



Quality

- EN ISO 13485:2012 +AC:2012
- Forward and backward traceability from donor through to final distribution
- Each serum and plasma donor unit is tested negative for Anti-HIV1/2, Anti-HBsAg, Anti-HCV, Anti-HIV-1 (NAT), Anti-HCV (NAT) and Anti-RPR
- Analyzed and inspected for conformity to customer specifications

Consistency

- 15+ years of experience in providing consistent products
- Highly skilled and trained professionals
- Raw material selection process
- Validated processes
- Quality control, inspection and testing ensure consistent products
- High homogeneity according to ISO 13528

Capabilities

- 10,000 liters of processed plasma yearly
- Ultrafiltration equipment with $> 7 \text{ m}^2$ membrane surface
- Modular filtration equipments from 1 to 8 cartridges housing
- Microfiltration equipment for $0.2 \mu\text{m}$ from 1 to 8 cartridges housing
- Sheet Press filters equipment for clarification and prefiltration processes
- Two automated filling lines with approximately 20,000 vials / hour
- Three freeze dryers from 8,000 to 35,000 vials capacity
- 100,000 vials storage capabilities at $-70 \text{ }^\circ\text{C}$

We offer:

- Screening of each plasma donation
- Defibrination
- Delipidation
- Charcoal Treatment
- Protein Fractionation
- Protein Purification
- Centrifugation
- Diafiltration / Dialysis
- Concentration
- Clarification / Depth Filtration
- Membrane Filtration
- Filling
- Lyophilisation
- Custom Packaging and Labelling
- Storage



	Abbr.*		Abbr.*
17 alpha-hydroxyprogesterone	17-OHP	Estriol	E3
Acetaminophen	APAP	Follicle-stimulating hormone	FSH
Acid phosphatase	ACP	Gamma-glutamyl transferase	GGT
Activated Partial Thromboplastin Time	aPTT	Glutamate Dehydrogenase	GLDH
Adrenocorticotrophic hormone	ACTH	Glutamic-Oxaloacetic Transaminase	GOT (AST)
Alanine aminotransferase	ALT (GPT)	Glutamic-Pyruvic Transaminase	GPT (ALT)
Albumin	ALB	Hemoglobin	Hb
Alkaline phosphatase	ALP	Hemoglobin A1c	HbA1c
Alpha-1 antitrypsin	AAT	Human growth hormone	hGH
Alpha-fetoprotein	AFP	Immunoglobulin A	IgA
Amylase	AMY	Immunoglobulin E	IgE
Antistreptolysin O	ASO	Immunoglobulin G	IgG
Antithrombin III	AT III	Immunoglobulin M	IgM
Apolipoprotein A1	Apo A-I	Lactate dehydrogenase	LDH
Apolipoprotein B	Apo B	Leucine aminopeptidase	LAP
Aspartate transaminase	AST (GOT)	Lipase	LPS
Blood urea nitrogen	BUN	Lipoprotein (a)	Lp(a)
B-type natriuretic peptide	BNP	Luteinizing hormone	LH
Cancer Antigen	CA	N-acetylprocainamide	NAPA
Carbamazepine	CBZ	Non-esterified fatty acids	NEFA
Carcinoembryonic antigen	CEA	N-terminal proBNP	NT-proBNP
Ceruloplasmin	CP	Parathyroid hormone	PTH
Cholinesterase	CHE	Protein, total	TP
Copeptin	CT-proAVP	Prothrombin time	PT
C-reactive protein	CRP	Retinol-binding protein	RBP
Creatine kinase	CK	Rheumatoid factor	RF
Creatine kinase-MB	CK-MB	Soluble transferrin receptor	sTfR
Creatinine	CREA	thyroid-stimulating hormone	TSH
Cytokreatin 19 fragment	Cyfra 21-1	total bilirubin	TBIL
Dehydroepiandrosterone sulfate	DHEAS	Transferrin	TRF
direct reacting bilirubin	DBIL	Unsaturated Iron Binding Capacity	UIBC
Estradiol	E2	α -hydroxybutyrate dehydrogenase	HBDH

*Tietz Textbook of Clinical Chemistry and Molecular Diagnostics
 Encyclopedia of Toxicology



OUR GUIDING PRINCIPLE:

DIRECT CONTACT WITH YOU

WITH US, YOUR PROJECT IS IN SAFE HANDS

Together we will find the best solution – Just try us now!

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