

**Sample Safety Information for
Quality Assessment Specimens in the Field of Clinical Chemistry**

1. Identification of substance/ mixture and company

1.1 Company INSTAND e.V.
 Ubierstr. 20
 40223 Düsseldorf, Germany

Telephone: +49 (0) 211 159 213 0
 (9.00 – 13.00 hours and
 14.00 – 15.00 hours)

1.2 Product

(Simulated) clinical specimens for detection of clinical chemistry parameters in medical laboratories as described in the scheme type or in the instruction sheet with individual distributions.

1.3 Exceptions

Urine sediments are pictures of the specimens, Ammonia is an Ammonium chloride solution and the photometer controls are potassium picrate solutions.

2. Hazards Specifications

Group ID	Scheme name	Health hazard information
630	ACE (Angiotensin-Converting-Enzyme)	This preparation contains human serum whose donors were tested negative for HIV, HCV and HBV. All controls of human origin should be considered as potentially infectious and treated with appropriate care.
750,	Markers of Ethanol Abuse 1	This preparation contains human serum whose donors were tested negative for HIV, HCV and HBV. All controls of human origin should be considered as potentially infectious and treated with appropriate care.
751	Markers of Ethanol Abuse 2	This preparation contains human urine whose donors were tested negative HIV, HCV and HBV. All controls of human origin should be considered as potentially infectious and treated with appropriate care.
710	Amino Acid Analysis	This preparation contains human plasma whose do-

Prüfungs- und Freigabeprotokoll		Name:	Erstellt am:	Unterschrift:
erstellt:		Dr. N. Wojtalewicz	20.02.2019	
geprüft:		D. Illigen	22.02.2019	
Leitung zur Freigabe:		Prof. I. Schellenberg	25.02.2019	
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Group ID	Scheme name	Health hazard information
		nors were tested negative for HIV, HCV and HBV. All controls of human origin should be considered as potentially infectious and treated with appropriate care.
118	Ammonia	No risk for health or environment in the used concentrations.
322	Infection Serology – C-Reactive Protein	This preparation contains human serum whose donors were tested negative for HIV, HCV and HBV All controls of human origin should be considered as potentially infectious and treated with appropriate care.
185	Biogenic Amine in Plasma	This preparation contains human plasma whose donors were tested negative for HIV, HCV and HBV. All controls of human origin should be considered as potentially infectious and treated with appropriate care.
760	Myocardial Markers	This preparation contains human serum whose donors were tested negative for HIV, HCV and HBV. All controls of human origin should be considered as potentially infectious and treated with appropriate care.
761	Myocardial Markers BNP	This preparation contains a synthetic matrix with added human BNP-32. Since no human body liquid is added, the samples were not tested for pathogens.
141	Serum Proteins /Electrophoresis	This preparation contains human serum whose donors were tested negative for HIV, HCV and HBV. All controls of human origin should be considered as potentially infectious and treated with appropriate care.
700	Ethanol	This preparation contains human serum whose donors were tested negative for HIV, HCV and HBV.



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Group ID	Scheme name	Health hazard information
		All controls of human origin should be considered as potentially infectious and treated with appropriate care.
130	Faecal-Diagnostics 01 – Calprotectin	This preparation contains human feces that was tested negative for salmonella, yersinia, shigella and campylobacter using the TPE-test. Samples were not tested for HIV, HCV or HBV. All controls of human origin should be considered as potentially infectious and treated with appropriate care.
131	Faecal-Diagnostics 02 – Hb, Hp-Hapto.-Complex	This preparation contains human feces that was tested negative for salmonella, yersinia, shigella and campylobacter using the TPE-test. Samples were not tested for HIV, HCV or HBV. All controls of human origin should be considered as potentially infectious and treated with appropriate care.
146	Fructosamine	This preparation contains human serum whose donors were tested negative for HIV, HCV and HBV. All controls of human origin should be considered as potentially infectious and treated with appropriate care.
243	Gammopathies	This preparation contains human plasma whose donors were tested negative for HIV, HCV and HBV. All controls of human origin should be considered as potentially infectious and treated with appropriate care.
111	Glucose – Conventional Analysis	This preparation contains human serum whose donors were tested negative for HIV, HCV and HBV. All controls of human origin should be considered as potentially infectious and treated with appropriate



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Group ID	Scheme name	Health hazard information
		care.
500	Urinary Stone Analyses	This preparation contains human kidney stones that were not tested for HIV, HCV or HBV. All controls of human origin should be considered as potentially infectious and treated with appropriate care.
244	IgG Subclasses	This preparation contains human serum whose donors were tested negative for HIV, HCV and HBV. All controls of human origin should be considered as potentially infectious and treated with appropriate care.
102	Capillary Zone Electrophoresis	This preparation contains human serum whose donors were tested negative for HIV, HCV and HBV. All controls of human origin should be considered as potentially infectious and treated with appropriate care.
100	Clinical Chemistry – Conventional Analysis	This preparation contains human serum whose donors were tested negative for HIV, HCV and HBV. All controls of human origin should be considered as potentially infectious and treated with appropriate care.
151	Lipids/ Lipidproteins	This preparation contains either human serum or plasma whose donors were tested negative for HIV, HCV and HBV. All controls of human origin should be considered as potentially infectious and treated with appropriate care.
110	Neonatal Bilirubin	This preparation contains human serum whose donors were tested negative for HIV, HCV and HBV. All controls of human origin should be considered as potentially infectious and treated with appropriate
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Group ID	Scheme name	Health hazard information
		care.
181	Photometer Controls	No risk for health or environment in the used concentrations.
241	Plasmaproteins 01	This preparation contains human plasma whose donors were tested negative for HIV, HCV and HBV. All controls of human origin should be considered as potentially infectious and treated with appropriate care.
242	Plasmaproteins 02 – Cystatin-C	This preparation contains human plasma whose donors were tested negative for HIV, HCV and HBV. All controls of human origin should be considered as potentially infectious and treated with appropriate care.
240	Plasmaproteins – hsCRP	This preparation contains human plasma whose donors were tested negative for HIV, HCV and HBV. All controls of human origin should be considered as potentially infectious and treated with appropriate care.
292	Tumor Markers	This preparation contains human serum whose donors were tested negative for HIV, HCV and HBV. All controls of human origin should be considered as potentially infectious and treated with appropriate care.
299	Tumor Marker - Calcitonin	This preparation contains a synthetic matrix and proteins of human origin. It was not tested for HIV, HCV and HBV. All controls of human origin should be considered as potentially infectious and treated with appropriate care.

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Group ID	Scheme name	Health hazard information
293	Tumor Markers – PSA + Testosterone	<p>This preparation contains human serum whose donors were tested negative for HIV, HCV and HBV.</p> <p>All controls of human origin should be considered as potentially infectious and treated with appropriate care.</p>
290	Vitamins (Serum)	<p>This preparation contains human serum whose donors were tested negative for HIV, HCV and HBV.</p> <p>All controls of human origin should be considered as potentially infectious and treated with appropriate care.</p>
291	Vitamins (Whole Blood)	<p>This preparation contains human serum whose donors were tested negative for HIV, HCV, HBV, HAV, B19V and Syphilis.</p> <p>All controls of human origin should be considered as potentially infectious and treated with appropriate care.</p>
296	Vitamins 03 – Vitamin C	<p>This preparation contains human serum whose donors were tested negative for HIV, HCV, HBV, HAV, B19V and Syphilis.</p> <p>All controls of human origin should be considered as potentially infectious and treated with appropriate care.</p>
187	Vitamins 04 – Methylmalonic Acid	<p>This preparation contains human serum whose donors were tested negative for HIV, HCV, HBV, HAV, B19V and Syphilis.</p> <p>All controls of human origin should be considered as potentially infectious and treated with appropriate care.</p>
245	Complement Analysis 01	<p>This preparation contains human serum whose donors were tested negative for HIV, HCV and HBV.</p>



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Group ID	Scheme name	Health hazard information
		All controls of human origin should be considered as potentially infectious and treated with appropriate care.
246	Complement Analysis 02	This preparation contains human serum whose donors were tested negative for HIV, HCV and HBV. All controls of human origin should be considered as potentially infectious and treated with appropriate care.
247	Complement Analysis 03	This preparation contains human plasma whose donors were tested negative for HIV, HCV and HBV. All controls of human origin should be considered as potentially infectious and treated with appropriate care.
248-250	Complement Analysis 04-06	This preparation contains human serum whose donors were tested negative for HIV, HCV and HBV. All controls of human origin should be considered as potentially infectious and treated with appropriate care.
145	HbA1c	This preparation contains human whole blood whose donors were tested negative for HIV, HCV and HBV. All controls of human origin should be considered as potentially infectious and treated with appropriate care.

3. Composition / Information on Ingredients

Group ID	Scheme name	Information on components	Biological Substance
630	ACE (Angiotensin-Converting-Enzyme)	Stabilized human serum samples	Category B

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Group ID	Scheme name	Information on components	Biological Substance
759	Markers of Ethanol Abuse 1	Native lyophilized serum off the clot from human source.	Category B
751	Markers of Ethanol Abuse 2	Native lyophilized human serum	Category B
710	Amino Acid Analysis	Native lyophilized human plasma	Category B
118	Ammonia	Ammonium sulfate in aqua dest.	
322	Infection Serology – C-Reactive Protein	Native human serum	Category B
185	Biogenic Amine in Plasma	Native lyophilized human plasma	Category B
760	Myocardial Markers	Native lyophilized human serum with added human myocardial markers	Category B
761	Myocardial Markers BNP	Lyophilized synthetic matrix with added human BnP-32	Category B
141	Serum Proteins /Electrophoresis	Native lyophilized human serum	Category B
700	Ethanol	Human serum spiked with ethanol in different physiological concentrations	Category B
130	Faecal-Diagnostics 01 – Calprotectin	Native lyophilized human feces	Category B
131	Faecal-Diagnostics 02 – Hb, Hp-Hapto.-Complex	Native lyophilized human feces	Category B
146	Fructosamine	Lyophilized human serum samples with added fructosamine	Category B
243	Gammopathies	Lyophilized human plasma with anticoagulant acid-citrate-dextrose and calcium chloride	Category B
111	Glucose – Conventional Analysis	Native lyophilized human serum	Category B
500	Urinary Stone Analyses	Pulverized human kidney stones	Category B
244	IgG Subclasses	Native lyophilized human serum	Category B
102	Capillary Zone Electrophoresis	Native lyophilized human serum	Category B
100	Clinical Chemistry – Conventional Analysis	Native lyophilized human serum	Category B



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Group ID	Scheme name	Information on components	Biological Substance
151	Lipids/ Lipoproteins	Lyophilized human plasma with inorganic salts Or lyophilized native human serum	Category B
110	Neonatal Bilirubin	Human serum spiked with bilirubin in different physiological concentrations	Category B
181	Photometer Controls	Potassium picrate in aqua dest.	
241	Plasmaproteins 01	Human native plasma	Category B
242	Plasmaproteins 02 – Cystatin-C	Human native plasma	Category B
240	Plasmaproteins – hsCRP	Human native plasma	Category B
292	Tumor Markers	Human serum with less than 1 % murine serum and 0,02 % sodium azide	Category B
299	Tumor Marker - Calcitonin	A lyophilized synthetic matrix with added human calcitonin and proGRP	Category B
293	Tumor Markers – PSA + Testosterone	Human serum with added 0,02 % sodium azide	Category B
290	Vitamins (Serum)	Lyophilized serum spiked with vitamins in different physiological concentrations	Category B
291	Vitamins (Whole Blood)	Human lyophilized whole blood spiked with vitamins in different physiological concentrations	Category B
296	Vitamins 03 – Vitamin C	Human lyophilized plasma with spiked vitamin c in different physiological concentrations	Category B
187	Vitamins 04 – Methylmalonic Acid	Human lyophilized plasma with spiked methylmalonic acid in different physiological concentrations	Category B
245	Complement Analysis 01	Native human serum	Category B
246	Complement Analysis 02	Native lyophilized human serum	Category B
247	Complement Analysis 03	Native lyophilized human plasma with EDTA	Category B
248 -250	Complement Analysis 04-06	Native human serum	Category B
145	HbA1c	Native human whole blood with K ₂ EDTA	Category B



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4. First Aid Measures

If accidental contact with material occurs laboratory staff must follow local first aid procedures that are normally applied following exposure to an equivalent clinical specimen. Medical advice should be sought following exposure to the material.

5. Fire Fighting Measures

Not applicable.

6. Accidental Release Measures

Personal precautions:

Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during handling.

Methods for cleaning up:

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. If samples are spilled, decontaminate by using a suitable surface disinfectant. Afterwards contain and collect carefully using suitable absorbent materials. Clean up surface with water after disinfection.

Environmental precautions:

Material must not end up in sewage, waters or soil.

7. Handling and Storage

Handling:

Avoid skin and eye contact. Wear personal protective equipment. Handle and open with care.

Storage:

Please store the samples according to the information on the sample tube or in the instruction sheet with individual distributions.

8. Exposure Controls/Personal Protection

Exposure limits:

No exposure limits noted for ingredients.

Exposure guidelines:

Follow standard monitoring procedures.

Personal protective equipment:

Have a safety shower and eye shower ready. Normal Good Laboratory Practices operating conditions are advised. No personal respiratory protective equipment is normally required. Wash hands with disinfectant soap and water after finishing laboratory work and before leaving the laboratory. Preventive skin protection is recommended. Use disposable gloves as minimum hand protection. A lab coat is recommended as appropriate protective clothing. Remove con-

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taminated clothing and wash before reuse. Wear chemical safety glasses as minimum eye protection.

9. Stability and Reactivity**Stability:**

Stable under normal conditions. Please find further information about the stabilities on the sample tube or the information sheet with individual distribution.

Reactive hazard:

No information available.

Hazardous reactions:

None under normal processing.

10. Toxicological Information

Not applicable.

11. Ecological Information

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

12. Disposal Consideration

After use, treat as biohazardous and environmentally hazardous material and dispose of material in accordance with current local, state and federal regulations.

13. Transport Information

Refer to national and international regulations for the transport of diagnostic specimens.

All specimen types can be transported within Germany and between Germany and overseas countries at ambient temperature and stored as described in section 7 upon arrival at their destination.

14. Regulatory Information

In accordance with Directive 1999/145/EC this material is non-dangerous.

15. Other Information

Materials for external quality measurements (proficiency tests) only The samples are not designed as standard or calibration material.