

### 3 MATERIALS RELATED TO CLINICAL CHEMISTRY

#### 3.1 PURE STANDARDS AND SYNTHETIC MATERIALS

	Description	Purity (%)
<b>BCR-546</b>	Formaldehyde 2,4-dinitrophenylhydrazone	> 99.3
<b>BCR-547</b>	Acetaldehyde 2,4-dinitrophenylhydrazone	98.3 ± 0.5
<b>BCR-548</b>	Acrolein 2,4-dinitrophenylhydrazone	> 97.9
<b>BCR-549</b>	Acetone 2,4-dinitrophenylhydrazone	> 99.6
<b>BCR-550</b>	Glutaraldehyde 2,4-dinitrophenylhydrazone	> 98.1

Availability: Approximately 10 mg of crystals in glass vials.

Compounds	<b>BCR-551</b> Acetonitrile solution Mass concentration (µg/mL)	<b>BCR-552</b> Acetonitrile solution (blank) (µg/mL)
Formaldehyde 2,4-Dinitrophenylhydrazone	2.94 ± 0.05	< 0.08
Acetaldehyde 2,4-dinitrophenylhydrazone	4.89 ± 0.07	< 0.05
Acrolein 2,4-dinitrophenylhydrazone	0.483 ± 0.011	< 0.04
Acetone 2,4-dinitrophenylhydrazone	4.96 ± 0.07	< 0.05

Availability: Set BCR-551-2 consists of 4 samples of BCR-551 and 1 sample of BCR-552.

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	<b>BCR-553</b> Glass fibre filters Spiked mass per filter (expressed as µg formaldehyde)	<b>BCR-554</b> Glass fibre filters Mass per filter (blank) (expressed as µg formaldehyde)
Formaldehyde 2,4-dinitrophenylhydrazine on glass fibre filters	4.96 ± 0.06	< 0.1

Availability: Set BCR-553-4 consists of 2 samples of BCR-553 and 1 sample of BCR-554.

Substance	<b>BCR-555</b> Chlorinated hydrocarbons on Tenax (ng)
Dichloromethane	320 ± 40
1,1,1-Trichloroethane	370 ± 40
Trichloroethylene	390 ± 40
Perchloroethylene	327 ± 17
Toluene	57 ± 7

Availability: Stainless steel tube of 9.0 cm length and 0.25 inches outer diameter containing a single section of 250 mg TENAX GR, charged with 4 chlorinated hydrocarbons and toluene at the levels shown above.

	<b>BCR-562</b> BTX-aromatic compounds on charcoal Mass of sorbed aromatic hydrocarbon on charcoal per charged tube (µg)
Benzene	15.0 ± 0.4
Toluene	147 ± 4
m-Xylene	96.4 ± 2.5
o-Xylene	93.0 ± 2.9

Availability: One set contains 20 glass tubes containing a single section of charcoal. Of these, six are charged with the four aromatic hydrocarbons at the levels shown above. Two have been opened and sealed in the same manner as the charged tubes, but have not been charged; these are intended as a means to check that no contamination occurred after sealing. The other 12 tubes are unopened as received from the manufacturer, and are intended for determining the desorption efficiency of the charcoal.

	Description	Latex spheres Parameters of the calibration line
<b>BCR-165</b>	Nominal 2 µm latex (0.02 % solids)	2.223 ± 0.013
<b>BCR-166</b>	Nominal 4.8 µm latex (0.2 % solids)	4.821 ± 0.019
<b>BCR-167</b>	Nominal 9.6 µm latex (1.4 % solids)	9.475 ± 0.018

Availability: Vials containing 2 mL of an aqueous suspension of latex spheres.

	Thyroxine (T <sub>4</sub> )	3,3',5-triiodothyronine (T <sub>3</sub> )
<b>IRMM-468</b>	98.6 ± 0.7	(0.51 ± 0.17)
<b>IRMM-469</b>	(1.50 ± 0.12)	97.1 ± 0.7

Values in brackets are not certified.

Availability: The material consists of an off-white crystalline powder in an amber glass vial sealed under N<sub>2</sub> atmosphere. Each vial contains about 100 mg of the powder.

## 3.2 MATRIX MATERIALS

### 3.2.1 CERTIFIED FOR THE HORMONE CONTENT

#### Cortisol reference panel of fresh frozen human sera ERM-DA451/IFCC

Serum No.	Certified value nmol/L	Uncertainty nmol/L	Serum No.	Certified value nmol/L	Uncertainty nmol/L
1	361	14	18	146	6
2	432	17	19	166	7
3	288	11	20	83	4
4	152	6	21	89	4
5	329	13	22	180	7
6	278	11	23	387	15
7	515	20	24	384	15
8	163	7	25	315	12
9	287	11	26	215	9
10	230	9	27	497	19
11	334	13	28	299	12
12	261	10	29	265	11
13	430	17	30	114	5
14	626	24	31	764	29
15	246	10	32	623	24
16	211	8	33	264	10
17	366	14	34	390	15

Availability: As panel of 34 x 1 mL serum in screw capped cryo-vials.

	Cortisol in human serum (concentration in the reconstituted material <sup>1)</sup> )					
	(µg/L)			(nmol/L)		
<b>ERM-DA192</b>	98.8	±	2.0	273	±	6
<b>ERM-DA193</b>	277	±	5	763	±	14

Availability: In units of lyophilised material of a 1.25 mL portion of serum kept under nitrogen in sealed glass ampoules.

<sup>1)</sup> The sample is to be reconstituted with (1.25 ± 0.01) mL of distilled water.

	Progesterone in human serum (concentration in the reconstituted material <sup>1)</sup> )					
	(µg/L)			(nmol/L)		
<b>BCR-348R</b>	8.5	±	0.4	26.9	±	1.2
<b>ERM-DA347</b>	3.19	±	0.07	10.13	±	0.21

Availability: In units of lyophilised material of a 1 mL portion of serum kept under nitrogen in sealed glass ampoules.

<sup>1)</sup> The sample is to be reconstituted with (1.0 ± 0.01) mL of distilled water.

	17β-Estradiol in human serum (concentration in the reconstituted material) Amount-of-substance concentration (nmol/L)					
<b>BCR-576</b> <sup>1)</sup>	0.114	±	0.005			
<b>BCR-577</b> <sup>2)</sup>	0.689	±	0.032			
<b>BCR-578</b> <sup>2)</sup>	1.34	±	0.07			

Availability: BCR-576, -577, -578 are lyophilised material of a 5 mL (BCR-576) or 1 mL (BCR-577 and BCR-578) portion of serum kept under nitrogen in sealed glass ampoules.

<sup>1)</sup> The sample is to be reconstituted with (5.00 ± 0.05) mL of distilled water.

<sup>2)</sup> The sample is to be reconstituted with (1.00 ± 0.01) mL of distilled water.

**3.2.2 CERTIFIED FOR THE TOTAL ELEMENT CONTENT AND OTHER PROPERTIES**

	Description	Substance	Metal concentrations in the reconstituted material <sup>1)</sup> (µg/L)		
<b>ERM-CE194</b>	Lyophilised bovine blood	Pb Cd <sup>2)</sup>	126 0.20	± ±	4 0.05
<b>ERM-CE195</b>	Lyophilised bovine blood	Pb Cd <sup>2)</sup>	416 5.06	± ±	9 0.15
<b>ERM-CE196</b>	Lyophilised bovine blood	Pb Cd <sup>2)</sup>	772 12.33	± ±	11 0.20
<b>BCR-634</b>	Lyophilised human blood	Pb Cd	46 1.4	± ±	5 0.4
<b>BCR-635</b>	Lyophilised human blood	Pb Cd	210 6.6	± ±	24 0.6
<b>BCR-636</b>	Lyophilised human blood	Pb Cd	0.52 · 10 <sup>3</sup> 11.6	± ±	0.05 · 10 <sup>3</sup> 0.6

Availability: In units of lyophilised material equivalent to about 5.75 mL of bovine blood with additives kept under nitrogen in rubber stoppered vials.

BCR-634, BCR-635 and BCR-636 are available in lyophilised form in brown glass vials, containing approximately 0.6 g dry matter equivalent to 3.0 mL of fresh whole blood.

<sup>1)</sup> The sample is to be reconstituted with (5.00 ± 0.01) mL water.

<sup>2)</sup> Recertified by IRMM.

	Description	Substance	Element concentration in the reconstituted material <sup>1)</sup> (mmol/L)		
<b>BCR-304</b>	Lyophilised human serum	Ca Li Mg	2.201 0.985 1.85	± ± ±	0.019 0.029 0.03

Availability: In units of lyophilised material equivalent to about 5.3 mL of human serum kept under vacuum in rubber stoppered vials.

<sup>1)</sup> The sample is to be reconstituted with (5.00 ± 0.01) mL bi-distilled water.

	Description	Substance	Metal concentrations (µg/L)		
<b>BCR-637</b>	Human serum	Al Se Zn	12.5 81 1110	± ± ±	3.0 7 220
<b>BCR-638</b>	Human serum	Al Se Zn	55 104 1430	± ± ±	7 7 210
<b>BCR-639</b>	Human serum	Al Se Zn	194 133 2360	± ± ±	14 12 140

Availability: supplied in frozen form in white plastic vials containing approximately 4.5 mL serum.

**3.2.3 CERTIFIED FOR PROTEIN CONTENT**

	Description	Mass concentration in the reconstituted material <sup>1)</sup> (g/L)		
<b>BCR-393</b>	Lyophilised Apo A I from human serum	1.06	±	0.05

Availability: In units of lyophilised material equivalent to about 1.5 mL of Apolipoprotein solution in sealed glass ampoules under nitrogen.

<sup>1)</sup> The sample must be reconstituted with 1.0 mL of phosphate buffer.

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	Description	Mass concentration in the reconstituted material <sup>1)</sup> (g/L)
<b>BCR-457</b>	Human Thyroglobulin (Tg)	0.324 ± 0.018

Availability: In units of lyophilised material in sealed glass ampoules under nitrogen.

<sup>1)</sup> The sample must be reconstituted with 1.0 mL of distilled water.

	Description	Protein mass per ampoule <sup>1)</sup> (µg)
<b>BCR-486</b>	Purified alphafoetoprotein (AFP)	100 ± 9

Availability: BCR-486 is provided in sealed glass ampoules. Each sample is in lyophilised form and it contains purified AFP without additives. The protein mass per ampoule is equivalent to (100 ± 9) µg when the material is reconstituted with 1.0 mL phosphate buffer according to the specified procedure.

<sup>1)</sup> Carbohydrate mass of the molecule is not included.

	Description	Protein mass/ampoule
<b>BCR-613</b>	Prostate specific antigen in the reconstituted material	71 ± 7 µg

Availability: Lyophilised PSA in sealed glass ampoules kept under argon gas.

	Description	HbA <sub>1c</sub> /Hb <sub>T</sub> in reconstituted material (g/kg)
<b>BCR-405 (RM)</b>	Glycated haemoglobin (HbA <sub>1c</sub> ) in human haemolysate	(62.9 ± 1.8)

Value in brackets is not certified.

Availability: Sealed glass ampoules of lyophilised material equivalent to about 0.5 mL of a solution of haemolysate of human erythrocytes kept under carbonmonoxide.

<sup>1)</sup> Sample to be reconstituted with 1 mL of deionised water and diluted with appropriate haemolyzing reagent, taking into account that the total haemoglobin (Fe<sub>4</sub>) concentration is about 0.23 mmol/L (15 g/L).

ERM-DA470k Human Serum Proteins			
Description	Mass concentration <sup>1)</sup> (g/L)	Description	Mass concentration <sup>1)</sup> (g/L)
α <sub>2</sub> macroglobulin (A2M)	1.43 ± 0.06	Haptoglobin (HPT)	0.889 ± 0.021
α <sub>1</sub> acid glycoprotein (AAG)	0.617 ± 0.013	Immunoglobulin A (IgA)	1.80 ± 0.05
α <sub>1</sub> antitrypsin (AAT)	1.12 ± 0.03	Immunoglobulin G (IgG)	9.17 ± 0.18
Albumin (ALB)	37.2 ± 1.2	Immunoglobulin M (IgM)	0.723 ± 0.027
Complement 3c (C3c)	1.00 ± 0.04	Transferrin (TRF)	2.36 ± 0.08
Complement 4 (C4)	0.162 ± 0.007	Transthyretin (TTR)	0.220 ± 0.018

Availability: Glass bottle containing lyophilised materials equivalent to about 1 mL of serum with additives kept under nitrogen.

<sup>1)</sup> Sample to be reconstituted with (1.00 ± 0.01) g water.

	Description	Mass concentration (mg/L)
<b>ERM-DA472/IFCC</b>	C-reactive protein (CRP)	41.8 ± 2.5

Availability: Glass ampoule containing at least 1 mL processed human serum spiked with CRP.

	Description	Absorbance at 540 nm and 10.00 mm pathlength	Mass concentration (mg/L)	Substance concentration (µmol/L)
<b>BCR-522</b>	Haemiglobincyanide (HiCN) in bovine blood lysate	0.5457 ± 0.0009	800.3 ± 1.3	49.61 ± 0.08

Availability: Bovine blood lysate in sealed brown glass ampoules (10 mL) equivalent to about 800.3 mg/L of haemiglobincyanide.

	Description	Amount-of-substance concentration of creatinine (μmol/L)		
<b>BCR-573</b>	Creatinine in human serum	68.7	±	1.4
<b>BCR-574</b>	Creatinine in human serum	105.0	±	1.3
<b>BCR-575</b>	Creatinine in human serum	404.1	±	7.1

Availability: BCR-573, -574, -575 are the lyophilised form of approximately 1 mL portion of serum, with no additives. The mass of the lyophilised material contained in the ampoule is about 0.09 g.

### BCR-573i (RM) Set of creatinine interfering substances

Availability: Consists of three vials with lyophilised solutions

- 0.025 mg calcium dobesilate / 1.2 mg cefoxitin;
- 0.044 mg sodium pyruvate;
- 0.108 mg bilirubin ditaurate.

	Description	Amount-of-substance fraction (mmol/mol)		
<b>IRMM/IFCC-466</b>	Haemoglobin isolated from whole blood	HbA1c/(HbA0 + HbA1c)	934	± 22
<b>IRMM/IFCC-467</b>	Haemoglobin isolated from whole blood	HbA0/(HbA1c + HbA0)	> 976	

Availability: Provided in vials containing approximately 39 mg a deep frozen buffered solution.

## 3.2.4 CERTIFIED FOR CATALYTIC ACTIVITY

	Description	Catalytic concentration in reconstituted material		Certified value
		U/L		
<b>BCR-410</b>	Prostatic acid phosphatase highly purified, from human prostate <sup>2)</sup>	28.0	± 0.7	0.466 ± 0.012
<b>BCR-647</b>	Human adenosine deaminase (ADA1), from human erythrocytes <sup>2)</sup>			2.55 ± 0.09
<b>BCR-693</b>	Human pancreatic lipase from pancreatic juice <sup>4)</sup>			28.9 ± 1.2
<b>BCR-694</b>	Human pancreatic lipase (recombinant) <sup>4)</sup>			17.4 ± 1.0
<b>ERM-AD452/IFCC</b>	γ-Glutamyltransferase partially purified, from pig kidney <sup>3)</sup>	114.1	± 2.4	1.90 ± 0.04
<b>ERM-AD453/IFCC</b>	Human lactate dehydrogenase isoenzyme 1 <sup>3)</sup>	502	± 7	8.37 ± 0.12
<b>ERM-AD454/IFCC</b>	Alanine aminotransferase partially purified, from pig heart <sup>3)</sup>	186	± 4	3.09 ± 0.07
<b>ERM-AD455/IFCC</b>	Creatine kinase CK-MB from human heart <sup>3)</sup>	101	± 4	1.68 ± 0.07
<b>IRMM/IFCC-456</b>	Human pancreatic α-Amylase <sup>3)</sup>			9.1 ± 0.3
<b>ERM-AD457/IFCC</b>	Aspartate Transaminase (AST)	104.6	± 2.7	1.74 ± 0.05

Availability: Sealed glass ampoules of lyophilised material equivalent to about 1 mL of a solution of enzyme stabilized by incorporation in serum albumin matrix of human (BCR-410 and ERM-AD453/IFCC) or bovine (ERM-AD452/IFCC, ERM-AD454/IFCC and ERM-AD457/IFCC) origin kept under dry nitrogen. BCR-647 has been stabilised by incorporation in a matrix of 50 mmol/L Tris/HCl buffer 9pH=7.4) and human serum albumin (30 g/L). ERM-AD455/IFCC and IRMM/IFCC-456 are provided in sealed ampoules or vials filled with dry nitrogen. Samples are in lyophilised form and equivalent to about 1 mL of a solution of purified enzyme.

BCR-693 and BCR-694 are provided in ampoules of lyophilised material equivalent to about 1 mL of stabilised enzyme.

- <sup>1)</sup> According to IFCC recommended method at 30 °C.
- <sup>2)</sup> According to method specified in report.
- <sup>3)</sup> According to IFCC recommended method at 37 °C.
- <sup>4)</sup> According to method described in certification report at 37 °C.

**3.2.5 CERTIFIED FOR DNA SEQUENCE**

	Plasmid DNA	
<b>IRMM/IFCC-490</b>	Sequence of 609 bp DNA fragment from human prothrombin gene (G20210 wildtype sequence)	$p < 3 \times 10^{-6}$
<b>IRMM/IFCC-491</b>	Sequence of 609 bp DNA fragment from human prothrombin gene (point mutation G20210A)	$p < 3 \times 10^{-6}$
<b>IRMM/IFCC-492</b>	Sequence of 609 bp DNA fragments from human prothrombin (G20210 wildtype and point mutation G20210A sequences)	$p < 3 \times 10^{-6}$

Availability: Each polypropylene vial contains approximately 1 ng plasmid DNA in a volume of 50 µL of a Tris/EDTA solution.

**3.2.6 OTHERS**

	Description	Parameters of the calibration line			
<b>ERM-AD148</b>	Lyophilised thromboplastin Bovine (OBT/79)	Slope	1.011	±	0.015
		intercept	- 0.321	±	0.025
<b>ERM-AD149</b>	Lyophilised rabbit thromboplastin	Slope	1.257	±	0.013
		Intercept	- 0.242	±	0.019

Availability: ERM-AD148 in units of lyophilised bovine brain thromboplastin equivalent to about 2.2 g bovine brain tissue extract kept under vacuum in sealed glass ampoules.  
ERM-AD149 in sealed glass ampoules containing the lyophilised form of a 0.5 mL aliquot of the extract of rabbit brain tissue, without calcium ion added.

	<b>BCR-665</b> Asbestos fibres in lung tissue (Number of fibres of more than 1 µm in length in million per g dry tissue)	<b>BCR-666</b> Asbestos fibres in lung tissue (Number of fibres of more than 1 µm in length in million per g dry tissue)
Amosite + crocidolite	49 ± 16	2.3 ± 0.9
Anthophyllite	1.8 ± 0.9	5.1 ± 1.5

Availability: Sealed vials with 100 mg of lung tissue.

	<b>IRMM-435</b> Pharmaceutical glass containers Alkali leaching and release
Volume of titration solution 0.01 mol/L HCl per 50 mL of leachate	0.38 ± 0.04 mL
Sodium release per volume of leachate	1.41 ± 0.14 mg/L
Release of Na <sub>2</sub> O per volume of leachate	1.91 ± 0.19 mg/L

Availability: Each unit of IRMM-435 consists of 20 vials of 18.9 mL brimful capacity, made of a semi-durable type of glass, which screw caps.