Higher order reference materials 2008/2009





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Reference Materials of Higher Order

The 2008 edition of the LGC Standards catalogue "Higher order reference materials" is the first in a new series. This catalogue includes a special range of reference materials, mainly from national metrology institutes.

The information provided in this catalogue has, wherever possible, been taken from electronic sources provided to LGC Standards by our suppliers, rather than transcribed from printed texts. Original descriptions and spellings are retained. In some cases additional information has been added to make the lists easier to use.

The catalogue is primarily intended for reference laboratories, IVD manufacturers and R&D facilities. It can also be used by laboratories that wish to evaluate the performance of routine measuring systems, therefore needing reference materials with small uncertainty and documented metrological traceability.

About LGC Standards

LGC Standards offers Europe's most comprehensive source of reference materials from the world's leading producers and this range "higher order reference materials" represents an important section of our product portfolio.

Our many years' experience in reference materials and associated analysis enables us to provide high levels of customer service and technical support. For example, assisting customers with the often time consuming task of locating the most appropriate materials for their application needs.

Our network of European offices and relationships with key reference materials suppliers throughout the world allows us to provide short delivery times and advice on differing requirements for the importation of reference materials.

About higher order reference materials

The term "higher order" stems from the European directive on in vitro diagnostic (IVD) medical devices (directive 98/79/EC). It includes primary calibrators, i.e. materials which are used to calibrate reference measurement procedures.

Higher order reference materials are produced by institutes or international organisations with responsibility for metrological traceability. The materials have been thoroughly characterised using the best available measurement procedures, sometimes as part of an interlaboratory comparison between national metrology institutes. The uncertainty of the materials' property values should, therefore, be the smallest attainable.

Most higher order reference materials are not intended for direct use by routine laboratories. Apart from such factors as cost and availability, the materials' matrix properties may not fit routine measuring systems. Instead these materials are used, e.g. by reference laboratories to calibrate secondary reference measurement procedures, and procedures used by manufacturers of calibrators. The calibration hierarchy, from top to bottom, is called a traceability chain.

Higher order reference materials are primarily associated with clinical measurements. A Joint Committee for Traceability in Laboratory (JCTLM) has been set up, one of its tasks being to identify higher order reference materials. This catalogue has been checked against information provided by the JCTLM (<u>www.bipm.org</u>) until July 2008. It is, however, equally important to identify primary calibrators in other analytical fields. Future editions of this catalogue may, therefore, list materials used to calibrate measurements in other fields.

All higher order reference materials are sold with detailed certificates of analysis, where in addition to the certified properties, their associated uncertainty and metrological traceability, instructions for storage, handling and use are also described. Several producers, e.g. the IRMM, provide via their websites or on request, a certification report. This is a detailed report about manufacturing, quality control and certification procedures including the results from external organisations.

The production of higher order reference materials underpins the national and/or international measurement infrastructure. The producers have a key role in developing, supporting and promoting good measurement practice. The cost of production is partially covered by government or other funding and, therefore, the sales price does not fully represent the true cost of production, characterisation and certification.

LGC Standards and producers of higher order reference materials

We are proud to present in this new catalogue the range of higher order reference materials from LGC Ltd, and other national metrology institutes and international organisations worldwide.

CENAM (Mexico) is the national metrology institute of Mexico. Its objective is to support the different sectors of the society regarding present and future metrological requirements, the establishment of national measurement standards, and development of reference materials and dissemination of their accuracy by means of technological services of highest quality.

IRMM (European Commission) has been developing reference materials since the late 1960s. It is today one of the world's largest reference material producers offering more than 600 BCR®, IRMM and ERM® certified reference materials for applications in the fields of food and feed analysis, environmental analysis, engineering and health. BCR® is a registered trademark of the European Communities. The BCR office was established by the European Commission in 1973 with a mandate to organise certification of reference materials and to distribute them. Since 2002, IRMM is responsible for the management of all remaining BCR[®] reference materials. Together with BAM (Germany) and LGC (UK), IRMM has established the European Reference Material (ERM[®]) partnership. The ERM[®] trademark is a guarantee of high quality and is only granted for reference materials which have passed a peer evaluation. LGC Standards is an authorised distributor of IRMM reference materials and currently stocks more than 2000 units under controlled conditions.

LGC (UK) is Europe's largest, independent analytical laboratory providing chemical, biochemical and DNA based analysis. LGC serves markets in both the public and private sectors including food and agriculture, oil and chemicals, pharmaceuticals, environment, healthcare, life sciences and law enforcement. Its state-of-the-art laboratories have set up reference measurement procedures, which are used in the production of higher order reference materials. The Government Chemist function at LGC applies sound analytical science in the public interest, providing expert evidence and advice to Government and industry. A key statutory role is to act as referee analyst in cases of dispute.

Medichem (Germany) has more than twenty years' experience of development and production of in vitro diagnostic products. The company initially focussed on development of reagents for general clinical chemistry and blood alcohol analyses. Since 1989 it has collaborated with institutes for forensic medicine in the development of quality control materials for toxicological and forensic analyses. Medichem provides proficiency test materials for German and foreign schemes, and manufactures the well-known trademark products Medidrug and Medisafe.

NIBSC (UK) is currently the world's major producer and distributor of WHO International Standards and reference materials, thereby assuring effective use of vaccines, most biotechnology products in therapy and many other biologicals. NIBSC is part of the National Biological Standards Board, a non-departmental public body of the UK government, established, in 1975, as a Statutory Body by Act of Parliament. The Board is responsible for safeguarding and advancing public health by assuring the quality and safety of biologicals, through NIBSC.

NIM (China). Founded in 1955, the National Institute of Metrology (NIM) is China's national metrological institute and technical center for legal metrology, affiliated with the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ). As for other NMIs, the NIM is tasked with establishing, maintaining and improving national measurement standards and conducting research on relevant technologies to achieve more precise measurements.

NIST (USA) is a non-regulatory federal agency within the Commerce Department's Technology Administration. NIST's mission is to promote U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology in ways that enhance economic security and improve quality of life. NIST has provided measurement standards to industry and commerce for more than a century and many of its Standard Reference Materials (SRMs) qualify as higher order reference materials.

NMIA (Australia), a division within the Department of Industry, Tourism and Resources, is responsible for Australia's national infrastructure in physical, chemical, biological and legal measurements. NMIA provides the legal and technical framework for disseminating measurement standards, measurement expertise, calibration services, chemical and biological analyses, patterns approval testing; and supports Australia's standards and conformance infrastructure. NMIA is Australia's representative under the international measurement treaties that establish the International Committee for Weights and Measures and the International Organization of Legal Metrology.

NMIJ (Japan), the national metrology institute, is responsible for forming consistent policies concerning measurement standards and legal metrology. NMIJ conducts research and development activities related to measurement standards, provides metrological services, and represents Japan in international activities regarding measurement standards and legal metrology.

ReCCS (Japan) Standard Reference Center Foundation (former HECTEF SRC Foundation) aims at developing and issuing reference materials and is approved to be an ASNITE National Metrology Institute in medical field of which quality system meets ISO/IEC 17025 and ISO Guide 34.

Availability of products

Items listed in the catalogue may not always be available at the time of ordering. Should this situation arise, an LGC Standards representative will contact you and suggest an alternative product.

Please note that replacement products may differ in analytical profile and property values.

Handling and safety

All documentation for higher order reference materials meets the highest metrological requirements. The correct handling for the intended use is described in instructions, certificates, reports, and other accompanying documents. Special attention is paid to the uncertainty and the traceability of property values.

Some RMs are classified as hazardous. All necessary safety information, including possible risks to health, are described in detail in accompanying documents and/or material safety data sheets (MSDSs). Any hazardous RM should only be handled by a specially trained technician or member of staff.

All RMs based on human body fluids are tested for infectious diseases according to legal regulations. The test and the results thereof are specified in the documentation. However, as no test method can offer complete assurance, all human samples should be handled at bio-safety level 2 conditions.

All reference materials in this catalogue are for laboratory analytical use only and not for use in humans.

General ordering information

Prices and delivery procedures are shown in the price list that accompanies this catalogue, or are available from your local LGC Standards sales office. For products requiring special delivery procedures (cooled shipping, special licensing, controlled substances, etc.) additional charges will be applied. Please check with your local LGC Standards sales office for detailed procedures and transport charges where applicable. Unless otherwise agreed in advance and in writing, orders are accepted only against LGC Standards' terms and conditions of sale.

Once delivered to the customer, reference materials are non-returnable. For this reason it is very important for users to be certain that the product ordered meets their needs.

LGC Standards' technical staff is available to advice on the use and suitability of a particular product. Customers requiring assistance with the use or application of a particular reference substance should contact their local LGC Standards office, contact details are provided at the beginning of this catalogue.

Metrological traceability and calibration hierarchy

To be able to compare results over space and time, all individual results must be linked to some common metrological reference or measurement standard. These references, "anchor points", define what is correct. The reference can be the practical realisation of a defined measurement unit, a reference material or a measurement procedure.

A laboratory, as well as a producer of reference materials, must be able must demonstrate that there is a link to a metrological reference.



Generic example of a traceability chain (EN ISO 17511:2003). The ideal end-point (reference) of a traceability chain is the definition of an SI unit. In laboratory medicine, this is possible for quantities having well-defined components, e.g. electrolytes, metabolites, glucose, cholesterol, drugs, steroid hormones and some thyroid hormones. The calibration hierarchy extends downwards in the figure, and the metrological traceability of the result extends upwards towards the reference. Materials and procedures above the upper dotted line can be considered to be of higher order.

Glossary

Terms and definitions are taken from, or based on, ISO Guide 31:2000, ISO 17511:2003, ISO 15193:2002, ISO 15195:2003, and the ISO/IEC Guide 99:2007 (VIM).

Calibration: operation that, under specified conditions, in a first step establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication.

Certificate (reference material): document containing all the information which is essential to the use of a certified reference material.

Certified reference material: reference material, accompanied by documentation issued by an authoritative body and providing one or more specified property values with associated uncertainties and traceabilities, using valid procedures.

Combined standard uncertainty: standard measurement uncertainty that is obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement model.

Expanded uncertainty: product of a combined standard uncertainty and a factor larger than the number one.

International conventional calibrator: calibrator established by international agreement.

Measurement procedure: detailed description of a measurement according to one or more measurement principles and to a given measurement method, based on a measurement model and including any calculation to obtain a measurement result.

Metrological traceability: property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty.

Metrology: field of knowledge concerned with measurement.

Measurement uncertainty: non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used.

Primary calibrator: calibrator established without reference to another calibrator for the same kind-ofquantity.

Primary measurement standard: measurement standard established using a primary reference measurement procedure, or created as an artifact, chosen by convention.

Primary measurement procedure: measurement procedure used to obtain a measurement result without relation to a measurement standard for a quantity of the same kind.

Product calibrator (manufacturer's): calibrator established according to the manufacturer's standing measurement procedure calibrated by the manufacturer's working calibrator.

Reference measurement laboratory: laboratory that performs a reference measurement procedure and provides results with stated uncertainties.

Reference material: material, sufficiently homogeneous and stable with reference to specified properties, which has been established to be fit for its intended use in measurement or in examination of nominal properties.

Reference measurement procedure: measurement procedure accepted as providing measurement results fit for their intended use in assessing measurement trueness of measured quantity values obtained from other measurement procedures for quantities of the same kind, in calibration, or in characterizing reference materials.

Abbreviations

BAM	Bundesanstalt für Materialforschung (Federal Institute for materials research and testing, Germany)
BCR [®]	Bureau Communautaire de Reference. Registered trademark of IRMM
BIPM	International Bureau of Weights and Measures
CRM	Certified reference material
ERM [®]	European Reference Material. Registered trademark of IRMM, BAM and LGC
GTFCh	Gesellschaft für Toxikologische und Forensische Chemie (Society for Toxicological and Forensic Chemistry)
IFCC	International Federation of Clinical Chemistry and Laboratory Medicine
IRMM	Institute for Reference Materials and Measurements, Joint research centre of the European Commission
ISO	International organization for standardization
JCTLM	Joint Committee for Traceability in Laboratory Medicine
IVD	in vitro diagnostic
MSDS	Material safety data sheet
NIBSC	National Institute for Biological Standards and Control
NIM	National institute of metrology, China
NIST	National Institute of Sandards and Technology
NMI	National metrology institute
NMIA	National measurement institute of Australia
NMIJ	National metrology institute of Japan
R&D	Research and development
RM	Reference material
SFBC	Société Française de Biologie Clinique
SI	International system of units (Système International d'Unités)
SRM	Standard reference material. Registered trademark of NIST
VIM	International vocabulary of metrology Basic and general concepts and associated terms
WHO	World Health Organization

Coagulation factors

Code	Product	Unit
NIBSC93/768	Antithrombin in human plasma	amp.
	This material is the 2nd International Standard for Antithrombin, Plasma. It consists of ampoules containing approximately 1ml aliquots of freeze dried normal human plasma. This preparation was established in 1994 by the Expert Committee on Biological Standardization of the WHO. The overall mean functional and antigen potency which was assigned to the standard is 0.85 IU/ampoule.	
NIBSC99/826	Factors II, VII, IX and X in human plasma This material is the 3rd International Standard (WHO 2001) for Factors II, VII, IX and X, Plasma, It consists of ampoules containing approximately 1 mL aliquots of normal freeze-dried human plasma. FII - 0.91 IU/ampoule FVII - 1.00 IU/ampoule FIX - 0.86 IU/ampoule FX - 0.93 IU/ampoule	amp.
NIBSC03/116	Factor V in human plasma This material is the 1st International Standard for Factor V, Plasma. It consists of ampoules containing approximately 1 mL aliquots of freeze-dried pooled normal human plasma. This preparation was established in 2005 by the Expert Committee on Biological Standardization (ECBS) of the WHO. The assigned value for Factor V clotting activity is 0.74 IU/ampoule.	amp.
NIBSC02/150	Factor VIII and Von Willebrand factor in human plasma This material is the WHO 5th International Standard for Factor VIII and von Willebrand Factor in plasma. It consists of ampoules containing 1 ml aliquots of freeze-dried pooled fresh human plasma. The standard is intended to be used for the estimation of Factor VIII Clotting activity, Factor VIII Antigen, von Willebrand Factor Ristocetin Co-factor function, von Willebrand Factor Antigen, and von Willebrand Factor Collagen Binding function in human plasma. FVIII:C - 0.68 IU/ampoule FVIII:Ag - 0.94 IU/ampoule VWF:RG - 0.78 IU/ampoule VWF:RG - 0.94 IU/ampoule VWF:CB - 0.94 IU/ampoule	amp.
NIBSC04/102	Factor XI in human plasma This material is the 1st International Standard for Factor XI. It consists of ampoules containing approximately 1 mL aliquots of freeze-dried normal human plasma, This preparation was established in 2005 by the Expert Committee on Biological Standardization (ECBS) of the WHO. The value (functional activity) assigned to the material is 0.86 Ul/ampoule.	amp.
NIBSC02/206	Factor XIII in plasma This material is the WHO 1st International Standard for Blood Coagulation Factor XIII. It consists of ampoules containing aliquots of a freeze-dried plasma containing FXIII. This preparation was established by the Expert Committee on Biological Standardization (ECBS) of the WHO in 2004. The material is intended to be used in the measurement of FXIII (both activity and antigen - A2B2 complex) in plasma, and for calibration of secondary and/or in-house working FXIII plasma standards. The assigned values are: Activity potency - 0.91 IU/ampoule Antigen potency - 0.93 IU/ampoule	amp.
NIBSC98/612	Fibrinogen in human plasma This material is the 2nd International Standard for Fibrinogen. It was established by the Expert Committee on Biological Standardisation of the WHO in October 1999. The preparation consists of ampoules containing 1 ml aliquots of solvent/detergent treated pooled and freeze-dried human plasma. The material is intended to be used in the measurement of fibrinogen in plasma, and for calibration of secondary and/or in-house working standards of fibrinogen plasma. The assigned value (mass concentration) is 2.2 mg Fibrinogen/ml after reconstitution.	amp.
NIBSC02/342	Protein C in human plasma This material is the 2nd International Standard for Protein C. It consists of ampoules containing approximately 1 mL aliquots of freeze-dried normal human plasma, This material was established in 2006 by the Expert Committee on Biological Standardization (ECBS) of the WHO. Function - 0.85 IU/ampoule Antigen - 0.84 IU/ampoule	amp.
NIBSC03/228	Protein S in human plasma This material is the 2nd International Standard for Protein S. It consists of ampoules containing 1 ml aliquots of freeze-dried pooled fresh human plasma. This material has been assigned potencies for total and free Protein S antigen and for Protein S function. Total Protein S antigen - 0.83 IU/ampoule Free Protein S antigen - 0.81 IU/ampoule Protein S function - 0.77 IU per ampoule	amp.
ERM-AD148	Thromboplastin, bovine (OBT/79) The sample is the lyophilised form of an 2.2 g aliquot of bovine brain thromboplastin combined and is intended for prothrombin time determination on blood plasma. It is kept under vacuum in sealed glass ampoules. Parameters of the calibration line Prothrombin time slope	amp.

Drugs

Code	Product	Unit
ERM-AD149	Thromboplastin, rabbit	amp.
	The sample is the lyophilised form of an 0.5 mL aliquot of the extract of rabbit brain tissue, without calcium ion added and it is intended for the determination of the prothrombin time in human blood plasma in accordance with the described methodology. It is kept under nitrogen in sealed glass ampoules.	
	Parameters of the regression line	
	Prothrombin time slope 1.257 ± 0.013 Prothrombin time intercept	

Drugs

Code	Product					Unit
NMIAD736	Amphetamine HCI				CH3	50 mg
	Purity (mass fraction)	994+05%				oo mg
	This material is no longer available.			~	NH2 . HOI	
NIST-1508A	Benzoylecgonine (cocaine n	netabolite) in freez	e-dried urine			set (4 x 10 mL)
	This material is intended primarily for consists of four bottles of freeze dri bottle of blank freeze dried urine (no	or the determination of ed urine, one bottle ea ot detected).	benzoylecgonine (c ch of three differen	ocaine metabolite) in huma t levels of benzoylecgonin	an urine. It ne plus one	
	Analyte	low m	edium hię	gh		
	Benzoylecgonine		61 ± 6.8 31	5 ± 15 ng/mL		
NMIAD740	Cocaine base			H ₃ C,	,COOCH3	50 mg
	Purity (mass fraction)	. 98.23 ± 0.33 %				
NMIAD752	Heroin base			AcO	$\langle \uparrow \rangle$	50 mg
	Purity (mass fraction)	97.4 ± 1.0 %		0,,	H N-CH3	J
NMIAD830	N-Methylamphetamine HCl				CH3	50 mg
	Purity (mass fraction)	99.8 ± 0.4 %			H NHCH3.HCI	00g
	MDA (3.4-Methylenedioxyam	nhetamine HCL)		0~~	CH3	50 mg
110072	Purity (mass fraction)	$99.5 \pm 0.8 \%$		(L	NH2. HCI	oo nig
		athylonodioxyamp	otamina HCI)	-	H .HCI	50 mg
NINIAD192	Purity (mass fraction)	99 98 + 1 5 %		87.	N_	50 mg
		00.00 ± 1.0 /0		0~		
NMIAD408	Morphine base				HO	50 mg
	Purity (mass fraction)	93.9 ± 0.8 %			O, H, N, CH3	
Drugs in se	um					
NIST-1599	Anticonvulsant drug level as	say standard				set (4 x 5 mL)
	This material is certified for mass c processed human serum base. It is employed in clinical laboratories for evaluation of working or secondary r material is supplied as a set of four blank.	oncentrations of two ar intended for use in the the determination of the eference solutions prep different freeze-dried p	nticonvulsant drugs e calibration and sta nese drugs in serur ared either in-hous preparations, three	(valproic acid and carbama andardisation of procedur n. It can also be used for e or supplied commercial different mass concentrat	azepine) in es critical ly. This tions and a	
	Analytes Ic	w mediu	um	high		
	Valproic acid	.3	4.2142.).319.	5 ± 4.1 μg/mL 4 ± 0.9 μg/mL		
NIST-900	Antiepilepsy drug level assay	/ standard				set (4 x 5 mL)
	This material is certified for mass c phenobarbital and primidone) in a p standardisation of procedures empl for the critical evaluation of working commercially. One set contains fou three different concentration levels.	oncentrations of four a processed human seru oyed in clinical laborat or secondary reference r bottles with freeze-dr	ntiepilepsy drugs (p m base. It is intend ories for the detern re solutions prepare ied human serum,	bhenytoin, ethosuximide, ed for use in the calibratic nination of these drugs in ed either in-house or supp including a blank (0 μg / μ	on and serum, and ilied mL) and	
	Analytes	toxic	therapeutic	sub-therapeutic		
	Phenytonin	۳9/۱۱۱۲ 60 7 + 0 ۹	µg/m⊏ 16 7 + 0 3	μg/IIIL 4 2 + 0 1		
	Ethosuximide	174.7 ± 0.6				
	Phenobarbital	103.6 ± 0.3	21.6 ± 0.2	5.3 ± 0.2		
	Primidone	18.6 ± 0.7	8.1± 0.2	3.6 ± 0.1		

Electrolytes

Code	Product	Unit
Drugs in uri	ne	
NIST-2381	Morphine and codeine in urine	set (4)
	This material is intended primarily for verifying the accuracy of methods used for the determination of morphine and codeine in human urine. One set consists of four bottles of freeze-dried urine: one bottle each of three different analyte levels plus one bottle of blank urine (X_D : < 1).	
	Analytes low medium high ng/mL ng/mL ng/mL	
	$ \begin{array}{llllllllllllllllllllllllllllllllllll$	
NIST-2382	Morphine glucuronide in freeze dried urine	set (4)
	This material is intended primarily for verifying the accuracy of methods used for the determination of morphine that is present as a glucuronide in human urine. One set consists of four bottles of freeze-dried urine: one bottle each of three different analyte levels plus one bottle of blank urine (X _D : <1). The certified mass concentrations for morphine glucuronide in the reconstituted urine are given below as free morphine.	
	Analyte low medium high	
	Morphine	
NIST-1511	Multi-drugs of abuse in freeze-dried urine	3 x 25 mL
	This material is intended primarily for verifying the accuracy of methods used for the determination of morphine, codeine, cocaine, (benzoylecgonine), and marijuana metabolite (THC-9-COOH) and phencyclidine in human urine. One set consists of three bottles of freeze-dried urine with all of the analytes included in each bottle. There is no blank urine with this set.	
	Analytes	
	Morphine 309 ± 20 ng/mL THC-9-COOH 14.1 ± 0.8 ng/mL Codeine 288 ± 11 ng/mL Phencyclidine 20.7 ± 2.0 ng/mL Benzoylecgonine 162 ± 8 ng/mL Phencyclidine 20.7 ± 2.0 ng/mL	
NIST-1507B	THC-COOH in freeze dried urine	set (3)
	This material is intended primarily for verifying the accuracy of methods used for the determination of 11-nor-delta- 9-tetrahydrocannabinol-9-carboxylic acid (THC-9-COOH) in human urine. It consists of three bottles of freeze- dried urine: two bottles, each containing a different certified concentration of THC-9-COOH and one bottle of a urine blank (X _D : <1). The contents of each bottle must be reconstituted with 20.0 mL of organic-free or HPLC- grade water.	
	Analyte low medium	
	THC-9-COOH	

Electrolytes

Code	Product	Unit
NIST-915B	Calcium carbonate, clinical	20 g
	This material is intended for use as an analytical standard of known purity. It is intended primarily for use in the calibration and standardization of procedures for calcium (Ca) determinations employed in clinical analysis and for routine critical evaluation of the daily working standards used in these procedures. The certified values for this material are expressed as % mass fractions.	
	Certified value	
	CaCO ₃	
NIST-3109A	This material is intended for use as a primary calibration standard for the quantitative determination of calcium. A unit consists of five 10 mL sealed borosilicate glass ampoules of an acidified solution prepared gravimetrically to contain a known mass fraction of calcium. The solution contains nitric acid at a volume fraction of approximately 10 %. Certified value	5 x 10 mL
NIST-924A	Lithium carbonate (clinical)	30 a
	This material is intended primarily for use in the calibrations and standardisation of procedures. It is supplied in crystalline form.	3
	Certified purity (mass fraction) 99.867 ± 0.017 %	
NIST-3129A	This material is intended for use as a primary calibration standard for the quantitative determination of lithium. One unit consists of five 10 mL sealed borosilicate glass ampoules of an acidified aqueous solution prepared gravimetrically from high-purity lithium carbonate to contain a known mass fraction of lithium. The solution contains nitric acid at a volume fraction of approximately 1 %.	5 x 10 mL
	Certified value: 10.01 ± 0.04 mg/g	
NIST-929A	Magnesium gluconate dihydrate	5 g
	This material is intended for use as an assay standard for magnesium. The material is highly purified magnesium gluconate dihydrate [Mg($C_6H_{11}O_7)_2 \cdot 2H_2O$]	
	Certified value (mass fraction) Magnesium	

Electrolytes

Code	Product	Unit
NIST-3131A	This material is intended for use as a primary calibration standard for the quantitative determination of magnesium. One unit consists of 50 mL of a single element solution in a high density polyethylene bottle sealed in an aluminized bag. The solution is prepared gravimetrically to contain a known mass fraction of magnesium. The solution contains nitric acid at a volume fraction of approximately 10 %.	50 mL
	Certified value:	
NIST-918B	Potassium chloride	30 g
	This material is intended for use as an analytical standard of known purity. It is intended primarily for use in the calibration and standardization of procedures for potassium (K) and chloride (CI) determinations employed in clinical analysis and for routine critical evaluation of the daily working standards used in these procedures. The certified values for this material are expressed as % mass fractions	
	Certified value	
	K	
NIST-3141A	This material is intended for use as a primary calibration standard for the quantitative determination of potassium. One unit consists of 50 mL of a single element solution in a high density polyethylene bottle sealed in an aluminized bag. The solution is prepared gravimetrically to contain a known mass fraction of potassium. The solution contains nitric acid at a volume fraction of approximately 1 %.	50 mL
	Certified value: 10.011 ± 0.029 mg/g	
NIST-919B	Sodium chloride	30 g
	This material is intended for the production of saline solutions of accurately known concentration and the calibration of instrumentation and standardization of procedures used in the determination of sodium and chloride ions in clinical analysis. A unit consists of a single glass bottle containing 30 g of the material. The certified values are expressed as % mass fractions.	
	Certified value	
	NaCl	
NIST-3152A	This material is intended for use as a primary calibration standard for the quantitative determination of sodium. One unit consists of 50 mL of a single element solution in a high density polyethylene bottle sealed in an aluminized bag. The solution is prepared gravimetrically to contain a known mass fraction of sodium. The solution contains nitric acid at a volume fraction of approximately 1 %.	50 mL
	Certified value	
Electrolytes i	n serum	
HEC JCCRM111	Sodium, potassium and chloride in frozen human serum This material is primarily intended for use in evaluating the accuracy of serum (plasma) Na, K and Cl measurements with (direct and indirect) ion selective electrodes in clinical laboratory tests. Its major use applications are evaluation of routine ISE analyzers, and of newly developed ISE analyzers or ion selective electrodes. The material can also be used to assess the accuracy of serum Na, K measurements by flame spectrometry and serum CI measurements by routine coulometric titration.	unit
	Certified concentrations and uncertainties	
	Na K Cl High level ICCRM 111-5H 157.8 + 0.3 5.69 + 0.02 120.0 + 1.0 mmol//	
	Medium level JCCRM 111-5 M	
BCR-304	Calcium (II), Magnesium (II) and Lithium (I) in human serum Each sample is in lyophilised form equivalent to about 5.3 mL of human serum kept under vacuum in rubber stoppered vials. Amount-of-substance concentration in the reconstituted material Analytes	vial
	Ca2.201 ± 0.019 mmol/L	
	Li	
NIST-956B	Electrolytes in frozen human serum	set (6)
	This material is primarily intended for use in the calibration and validation of procedures and methods employed in clinical analysis for the determination of electrolytes in either diluted or undiluted human serum or plasma. It can be used for calibrating direct-reading ion-selective electrode analyzers [1] and for validating secondary reference materials. A unit consists of six sealed ampoules of frozen human serum, two ampoules each of three different concentration levels. Each ampoule contains approximately 2.0 mL of human serum. Certified values for elements at three levels.	
	Analytes level 1 level 2 level 3	
	Ca	
	Li	
	Mg0.994 \pm 0.0130.458 \pm 0.006 mmol/L	
	Na	

Enzymes

Code	Product			Unit
NIST-909B	Human serum			set (6x10 mL)
	This material is primarily specified constituents in A unit consists of six bott levels and six bottles of c clinical analytes; choleste	intended for use in evaluating the acc human serum. It can also be used to les of lyophilised human serum, three leionised, autoclaved water for reconserol, urea etc. are given in both mmol.	curacy of clinical procedures for determination of validate working or secondary reference materials bottles each of two different analyte concentration stitution. Certified values for trace metals and othe /L and mmol/L/g.	1 r
	Analytes	Level 1	Level 2	
	Calcium		3.532 ± 0.028 mmol/L	
	Chloride			
	Cholesterol	3.787 ± 0 047	6.084 ± 0.077 mmol/L	
	Creatinine	0.05618 ± 0.00055	0.4674 ± 0.0053 mmol/L	
	Lithium	0.6145 ± 0 0050	2.600 ± 0.023 mmol/L	
	Magnesium	0.7634 ± 0.0050	1.918 ± 0.021 mmol/L	
	Potassium		6.278 ± 0.052 mmol/L	
	Sodium	120.76 ± 0.92	141.0 ± 1.3 mmol/L	
	Total glycerides	0.949 ± 0.061	1.529 ± 0.035 mmol/L	
	Triglycerides	0.804 ± 0.011	1.271 ± 0.014 mmol/L	
	Urea	5.51 ± 0.15		
	Uric acid	0.277 ± 0.012 ±	0.733 ± 0.023 mmol/L	
	Uncertified (information)	values		
	ALP			
	LDH			
	ALT		150 U/L	
	AST			
	СК	9		
	pН	7.9 at 22.6 °C	7.8 at 22.9 °C	

Enzymes

Code	Product	Unit
ERM-AD454	Alanine aminotransferase	amp.
	Each sample is in lyophilised form and equivalent to about 1 mL of a solution of purified alanine aminotransferase from pig heart. The material is kept under dry nitrogen in sealed glass ampoules. Catalytic concentration of alanine aminotransferase in reconstituted material as determined by the IFCC method at 37 °C	
	Analyte	
	Alanine amminotransferase	
IRMM/IFCC 456	alpha-Amylase	amp.
	Each sample is in lyophilised form and equivalent to about 1 mL of a solution of a partially purified human pancreatic α -amylase. The material is kept under nitrogen gas in sealed glass ampoules. Catalytic concentration of α -amylase in reconstituted material as determined by the IFCC method at 37 °C	
	Analyte	
	α-Amylase946 ± 19 U/L 9.1± 0.3 μkat/L	
ERM-AD455	Creatine kinase (CK-MB Isoenzyme)	vial
	Each sample is in lyophilised form and equivalent to about 1 mL of a solution of purified creatine kinase from human heart. Material is kept under dry nitrogen gas in sealed glass ampoules. Catalytic concentration of creatine kinase-2 (CK-MB) in reconstituted material as determined by the IFCC method at 37 °C	
	Analyte	
	Creatine kinase-2 (CK-MB)101± 4 U/L 168 ± 0.07 μkat/L	
ERM-AD452	gamma-Glutamyltransferase	amp.
	Each sample is in lyophilised form and equivalent to about 1 mL of a solution of a partially purified pig kidney γ-glutamyltransferase. The material is kept under nitrogen gas in sealed glass ampoules. Catalytic concentration of γ-glutamyltransferase in reconstituted material as determined by the IFCC method at 37 °C.	
	Analyte	
	γ-Glutamyltransferase	
ERM-AD453	Lactate dehydrogenase isoenzyme 1	amp.
	Each sample is in lyophilised form and equivalent to about 1 mL of a solution of purified lactate dehydrogenase from human erythrocytes. The material is kept under dry nitrogen in sealed glass ampoules. Catalytic concentration of lactate dehydrogenase isoenzyme 1 in reconstituted material as determined by the IFCC method at 37 °C.	
	Analyte	
	Lactate dehydrogenase isoenzyme 1502 ± 7U/L 	

Code	Product	Unit
BCR-410	Prostatic acid phosphatase from human prostate	amp.
	Each sample is in lyophilised form and equivalent to about 1 mL of a solution of enzyme, stabilised by incorporation in a matrix of human serum albumin. Material is kept under dry nitrogen in sealed glass ampoules. Catalytic concentration of prostatic acid phosphatase in reconstituted material.	
	Analyte	
	Prostatic acid phosphatase	
Enzymes in	n serum	

 HEC JCERM20327
 Lactate dehydrogenase (LDH) in bovine serum albumine
 unit

 Lot No. 003 certified value (catalytic concentration) 398 ± 5 U/l
 U/l

Metabolites and substrates

Code	Product	Unit
NIST-2389	Amino acids mixture	set (5 x 2 mL)
	This material is a solution of 17 amino acids in a 0.1 mol/L aqueous solution of hydrochloric acid. It is intended primarily for the use in calibration of chromatographic instrumentation for the determination of amino acids. A unit of consists of five 2 mL ampoules each containing approximately 1.2 mL of the solution.	
	Amino acid concentration mmol/L Amino acid concentration mmol/L	
	Alanine 2.51 ± 0.09 Lysine 2.47 ± 0.10 Arginine 2.94 ± 0.14 Methionine 2.43 ± 0.09 Aspartic acid 2.50 ± 0.09 Phenylalanine 2.44 ± 0.08 Cystine 1.16 ± 0.04 Proline 2.44 ± 0.09 Glutamic acid 2.47 ± 0.08 Serine 2.43 ± 0.09 Glycine 2.47 ± 0.08 Threonine 2.39 ± 0.08	
	Histidine 2.83 ± 0.11 Tyrosine 2.47 ± 0.09 Isoleucine 2.39 ± 0.07 Valine 2.44 ± 0.08 Leucine 2.48 ± 0.09 Valine 2.44 ± 0.08	
ERM-AC401D	Aqueous ethanol - 80 mg / 100 mL	50 mL
	Mass concentration	
ERM-AC402B	Aqueous ethanol - 107 mg / 100 mL Mass concentration	25 mL
ERM-AC403B	Aqueous ethanol - 200 mg / 100 mL	25 mL
		100
NIS1-916A	This material consists of a sample of unconjugated bilirubin that is certified as a chemical of known purity. It is intended primarily for use in the calibration and standardization of procedures used for the determination of bilirubin in clinical samples and for routine evaluations of daily working standards used in these procedures. This material can also be used for quality assurance when assigning values to in-house control materials. Certified value (mass fraction)	roo mg
NIST-927D	Bovine serum albumin (7% solution)	10 x 2.1mL
	This material is intended primarily for use in the standardization of procedures employed in clinical analyses for total serum protein, for critical evaluation of daily working standards used in these procedures, and as a reference standard for assays of total protein by colorimetric methods. It is a solution (mass fraction 7 %) of known protein concentration and purity. The protein content of this material was determined using the biuret reference method that is recommended for use in standardizing laboratory-prepared protein solutions and "normal" serum pools. In addition to the measurement using the biuret method, NIST made measurements of the bovine serum albumine (BSA) concentration using amino acid analysis. A unit consists of 10 ampoules each containing 2.1 mL of solution.	
	Certified bovine serum albumine concentration by amino acid analysis BSA concentration	
	Reference total protein concentration by the biuret method Protein concentration	
NIST-911C	Cholesterol	2 g
	This material is intended primarily for use in the calibration and standardization of procedures for the determination of cholesterol in clinical samples and for routine evaluations of daily working standards used in these procedures. A unit consists of 2 g of material.	
	Certified purity (mass fraction)	
NMIJ CRM6001-9	Cholesterol	1 g
	This material is intended for the use in calibration of analytical instruments and validation of analytical techniques and instruments. Each unit contains 1 g of high purity cholesterol filled in amber borosilicate glass vials and an aluminized bag with argon gas.	
	Certified purity (mass fraction)	
NCS ZC76020B	Cholesterol (formerly GBW09203b) Certified purity	300 mg

Metabolites and substrates

Code	Product	Unit
NIST-914A	Creatinine This material is intended primarily for use in the calibration and standardisation of procedures used for	10 g
	determination of creatinine.	
	Certified purity (mass fraction)	
NIST-917B	D-Glucose (dextrose, clinical)	50 g
	This material is intended primarily for use in the calibration and standardisation of procedures for glucose determinations. Certified purity (mass fraction)	
CEN DMR-190	Glucose in powder	15 a
	This material is used for analytical calibration as well as method validation in high performance liquid chromatography with refraction index detector and electrochemical detector employed in glucose measurements. Each unit contains 15 g of glucose in crystals in a transparent glass bottle as a calibrant for quantified glucose.	
	Certified Purity (mass fraction)	
NIST-925	4-Hydroxy-3-methoxy-DL-mandelic acid (VMA), clinical This material is intended primarily for use in the calibration and standardisation of procedures employed in clinical analysis and for routine critical evaluation of the daily working standards used in these procedures.	1 g
		2 a
1031-1030	This material is intended primarily for use in the calibration and standardisation of procedures for the chemical analysis of serum for triglycerides, and for the critical evaluation of routine working or secondary reference materials used in these procedures.	2 y
	Certified purity (mass fraction)	
NIST-912A	Urea This material is certified as a chemical of known purity. It is intended primarily for use in the calibration and validation of procedures for uric acid determinations employed in clinical analysis.	25 g
	Certified purity (mass fraction) 99 ± 0.1 % Moisture 0.02 ± 0.003 % Biuret 0.02 ± 0.02 % Ash 0.001 ± 0.0007 % Insoluble matter 0.0001 ± 0.0005 %	
NCS ZC76009	Urea (formerly GBW09201) This material is a high-purity material intended for use as a primary calibrator for higher order reference measurement procedures.	6 g
	Certified purity 99.9 ± 0.2 %	
NIST-913A	Uric acid This material is certified as a chemical of known purity. It is intended primarily for use in the calibration and standardization of procedures for uric acid determinations employed in clinical analysis and for routine critical evaluation of the daily working standards used in these procedures. Certified purity (mass fraction)	10 g
NCS ZC76010	Uric acid (formerly GBW09202) This material is a high-purity material intended for use as a primary calibrator for higher order reference measurement procedures. Purity (mass fraction)	400 mg
Motabolitos a	nd substratos in sorum	
NIST-1952A	Cholesterol in human serum This material is intended for use in evaluating the accuracy of clinical procedures for the determination of cholesterol in serum, in calibrating instruments and equipment used in these procedures and in validating working or secondary standards. It consists of six vials of freeze-dried serum, two each of three different cholesterol levels. Concentrations are also given in mg/dL/g.	set (6)
	Analyte Iow medium high Cholesterol (mmol·l ⁻¹ ·o ⁻¹) 13.89 21.29 28.91	
	Cholesterol in human serum	unit
	This material is intended for use in evaluating the accuracy of total cholesterol assays in clinical laboratory testing and validating secondary or working reference materials. The material was prepared according to an NCCLS protocol to ensure that, while avoiding lipoprotein degradation, its properties would be the same as those of fresh serum. A single set of JCCRM 211-1 consists of four vials, two for each of the concentration levels (medium and high), each containing 0.5 ml of frozen human serum. Certified value JCCRM 211-11M	unit
	0001101211 101	

Code	Product	Unit	
NIST-967	Creatinine in frozen in human serum	set (4)	
	This material is intended primarily for use in evaluating the accuracy of procedures for the determination of creatinine in human serum and also for use in validating working or secondary reference materials. A unit consists of four stoppered ampoules of frozen human serum, two ampoules each at two different creatinine concentration levels. One level corresponds to the normal range of serum creatinine levels, and the second level is intended to correspond to levels found in chronic kidney desease. Each ampoule contains 1.0 mL of human serum.		
	Concentrations		
	Level I0.665 ± 0.0019 mmol/L Level II0.3462 ± 0.0073 mmol/L		
ERM-DA251A	Frozen human serum (low) (Creatinine and electrolytes in frozen human serum - low level)	vial	
	The material is intended for use in the validation and ongoing monitoring of methods of analysis for the determination of creatinine and electrolytes in human blood samples. Each units consists of 1 ml of human serum in a screw-cap plastic vial. (For further analytical information, see description of ERM-DA250A above)		
	Constituents certified value Constituents certified value Constituents certified value		
	Creatinine 22 ± 2 mg/kg Lithium 4.5 ± 0.3 mg/kg Potassium 136 ± 7 mg/kg Calcium 71 ± 3 mg/kg Magnesium 19 ± 2 mg/kg Sodium 2740 ± 80 mg/kg		
ERM-DA250A	Frozen human serum (Creatinine and electrolytes in frozen human serum - high level)	vial	
	This material is intended for use in the validation of new methods and monitoring the performance of methods commonly used in clinical laboratories to determine the creatinine and/or electrolyte content in human blood samples. They can also be used in the training and evaluation of staff. Measuring serum creatinine is the most commonly used indicator of renal function. Measurement of electrolytes is also a commonly performed diagnostic procedure. However, the interpretation of the electrolyte values is of limited value without parallel measurement of renal function. Therefore measurements of both creatinine and electrolytes tend to be carried out at the same time in clinical laboratories. This is the rationale for the production of reference materials containing both sets of analytes. Two of these materials (ERM-DA250A and ERM-DA251A) have been certified for both creatinine and electrolytes (calcium, lithium, magnesium, potassium and sodium). The remaining two materials (ERM-DA252A and ERM-DA253A) have been certified for creatinine only, although information on the levels of electrolytes is provided. The creatinine content of the four materials covers a wide spectrum: one is below the normal range; one is above the normal range, and two within the normal range. The creatinine content was certified using isotope-dilution liquid chromatography-tandem mass spectrometry (ID-LC/MS-MS), following spiking with isotopically-labelled (methyl-d3) creatinine, precipitation with absolute ethanol and filtration. LC was carried out on a C18 column with a mobile phase of 10 mM ammonium acetate. The electrolyte coupled plasma mass spectrometry (ID-ICP-MS) for calcium, lithium, potassium and sodium, and isotope dilution inductively-coupled plasma mass spectrometry (ID-ICP-MS) for calcium, lithium, potassium and sodium, and isotope dilution inductively-coupled plasma mass spectrometry (ID-ICP-MS) for magnesium. Each units consists of 1 ml of human serum in a screw-cap plastic vial.		
	Calcium		
ERM-DA252A	Creatinine in frozen human serum (low level)	vial	
	The material is intended for use in the validation and ongoing monitoring of methods of analysis for the determination of creatinine in human blood samples. Each units consists of 1 ml of human serum in a screw-cap plastic vial. (For further analytical information, see description of ERM-DA250A above)		
	Certified value (mass concentration)		
ERM-DA253A	Creatinine in frozen human serum (high level)	vial	
	The material is intended for use in the validation and ongoing monitoring of methods of analysis for the determination of creatinine in human blood samples. Each units consists of 1 ml of human serum in a screw-cap plastic vial. (For further analytical information, see description of ERM-DA250A above)		
	Certified value (mass concentration)		
BCR-573	Creatinine in human serum (low)	0.9 g	
	Each sample is 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.		
	Amount-of-substance concentration 68.7 ± 1.4 µmol/L		
BCR-574	Creatinine in human serum (medium)	0.9 g	
	Each sample is the lyophilised form of approximately 1 mL portion of serum, spiked with no further additives. The mass of the lyophilised material contained in the ampoule is about 0.09 g. Amount-of-substance concentration 105.0 ± 1.3 µmol/L		
BCR-575	Creatinine in human serum (high)	090	
	Each sample is the lyophilised form of approximately 1 mL portion of serum spiked with exogenous creatine, with no further additives. The mass of the lyophilised material contained in the ampoule is about 0.09 g. Amount-of-substance concentration $404.1 \pm 7.1 \mu$ mol/L	0.0 g	

Metabolites and substrates

Code	Product	Unit
NIST-968C	Fat soluble cholesterol and vitamins in human serum This material is intended for use in validating methods for determining fat-soluble vitamins, carotenoids, and cholesterol in human serum and plasma. It can also be used for quality assurance when assigning values to in- house control material for these constituents. A unit consists of two vials of lyophilised human serum, one vial at each of two different concentration levels.	set (2)
	Analytes level I level II ug/ml ug/ml	
	trans-retinol 0.841 ± 0.027 0.484 ± 0.012 δ-Tocopherol 0.131 ± 0.018 0.527 ± 0.071 γ-Tocopherol 3.90 ± 0.13 1.56 ± 0.10 α -Tocopherol 7.47 ± 0.47 16.79 ± 0.76 trans-β-carotene 0.157 ± 0.016 0.391 ± 0.047 Total β-carotene 0.171 ± 0.017 0.436 ± 0.034 Cholesterol 1335 ± 13 1669 ± 17	
NIST-965A	Glucose in frozen human serum	unit
	This material is intended primarily for determination of glucose in human serum. It is also intended for use in validating working or secondary reference materials. A unit of NIST-965a consists of eight flame sealed ampoules of frozen human serum, two ampoules at each of four different concentration levels. Each ampoule contains 2.00 ± 0.04 mL of human serum. Concentration levels mmol/L	
	Level 1 1.918 ± 0.020 Level 2 4.357 ± 0.048 Level 3 6.777 ± 0.073 Level 4 16.24 ± 0.19	
HEC JCCRM521	Glucose in human serum	unit
	Certified values (mass concentration) in the range 73.9 to 239 mg/l with corresponding uncertainties of 0.5 to 1.7 mg/l.	um
NIST-1955	Homocysteine and folate in frozen human serum	unit (3)
	This material is intended primarily for use in evaluating the accuracy of clinical procedures for the determination of homocysteine and folate (in various forms) in human serum. It is also intended for use in validating working or secondary reference materials. A unit consists of three bottles of frozen human serum, each of three concentration levels. Each bottle contains 1 mL of human serum. Certified values (amount-of-substance concentration and mass concentration): Concentration levels for Homocysteine	
	$\label{eq:molecular} \begin{array}{c} \mu \text{mol/L} & \dots & \mu \text{g/mL} \\ \text{Level I} & 3.98 \pm 0.18 & \dots & 0.538 \pm 0.024 \\ \text{Level II} & 8.85 \pm 0.60 & \dots & 1.196 \pm 0.082 \\ \text{Level III} & & 17.7 \pm 1.1 & \dots & 2.39 \pm 0.15 \\ \end{array}$	
	Level I 9.73 ± 0.24 1.96 ± 0.12 Level II 9.73 ± 0.24 4.47 ± 0.11	
NIST-1951B	Lipids in frozen human serum	unit (4 x 1mL)
	This material is intended primarily for use in evaluating the accuracy of clinical procedures for the determination of total cholesterol, HDL-cholesterol, LDL-cholesterol, and triglycerides (both total glyceride species and triglycerides only) in human serum. It is also intended for use in validating working or secondary reference materials. A unit consists of four bottles of frozen human serum, two bottles each of two different analyte concentration levels. Each bottle contains 1 mL of human serum. Concentrations are also given in mg/dL.	, , ,
	Analyte level I level II	
	Total Choissteroi 4.804 ± 0.014 6.895 ± 0.022 mmol/L Total Glycerides 1.370 ± 0.015 2.988 ± 0.036 mmol/L Triglycerides only 1.208 ± 0.013 2.700 ± 0.027 mmol/L	
CEN DMR-263A	Metabolites and substrates in frozen human serum (creatinine, cholesterol, glucose, urea, uric acid)	unit
	This material is intended for the calibration and validation of clinical procedures, and for preparation of secondary reference materials. It can also be used in calibration and validation of glucose procedures based on high performance liquid chromatography with refraction index and electrochemical detection. Each unit consists of one cryogenic vial of 1 mL serum.	
	Certified values Glucose	
	Creatinine	
	Urea	•-
HEC JCCRM223	I rigiveerides in numan serum Certified values (amount-of-substance concentration) in the range 1.04 mmol/l to 2.64 mmol/l with corresponding uncertainties of 0.03 to 0.07 mmol/l.	unit

Code	Product			Unit
HEC JCCLS021	Uric acid in fresh human	serum		unit
	This set of three materials are in human serum, and in valida concentration levels. The high the low level fresh pooled hum	primarily intended for use in e tion of secondary reference m er levels were prepared by ad nan serum. Certified values:	evaluating reference methods for determining uric acid aterials. It is certified for uric acid at three ding high purity creatinine, uric acid and glucose into	
	Medium concentration	High concentration	Abnormally high concentration	
	4.342 ± 0.010 mg/dl	7.496 ± 0.017 mg/dl	10.71 \pm 0.03 mg/dl	

	••••••••••••••••••••••••••••••••••••••			•••••	5.55 mg,
0.2583	± 0.0006 mmol/I	0.4460 ± 0	0.0010 mmol/l	0.6374 ± 0	.0014 mmol/l

Non-electrolyte metals

Non-electrolyte metals in blood

Code	Product	Unit
BCR-634	Lead and cadmium in reconstituted human blood (low)	vial
	The material is supplied in lyophilised form in brown glass vials. Sodium-EDTA was used as anticoagulant. No other preservatives were added. The content of a vial is approximately 0.6 g dry matter with residual moisture content less than 2 % and equivalent to 3.0 mL of fresh whole blood. This material was produced from blood from healthy Danish blood donors. Each portion of blood was tested negative for Anti-HIV-1&2, Anti-HCV and Anti- HTLV-I&II. However, as all biological material of human origin the blood should be treated as contagious material.	
	Analytes mass concentration	
	Cd 1.4 \pm 0.4 µg/L Pb 46 \pm 5 µg/L	
BCR-635	Lead and cadmium in reconstituted human blood (medium)	vial
	The material is supplied in lyophilised form in brown glass vials. Sodium-EDTA was used as anticoagulant. No other preservatives were added. The content of a vial is approximately 0.6 g dry matter with residual moisture content less than 2 % and equivalent to 3.0 mL of fresh whole blood. This material was produced from blood from healthy Danish blood donors. Each portion of blood was tested negative for Anti-HIV-1&2, Anti-HCV and Anti-HTLV-I&II. However, as all biological material of human origin the blood should be treated as contagious material.	
	Analytes mass concentration	
	Cd $6.6 \pm 0.6 \ \mu$ g/L Pb $210 \pm 24 \ \mu$ g/L	
BCR-636	Lead and cadmium in reconstituted human blood (high)	vial
	The material is supplied in lyophilised form in brown glass vials. Sodium-EDTA was used as anticoagulant. No other preservatives were added. The content of a vial is approximately 0.6 g dry matter with residual moisture content less than 2 % and equivalent to 3.0 mL of fresh whole blood. This material was produced from blood from healthy Danish blood donors. Each portion of blood was tested negative for Anti-HIV-1&2, Anti-HCV and Anti-HTLV-I&II. However, as all biological material of human origin the blood should be treated as contagious material.	
	Analytes mass concentration	
	Cd	
ERM-CE194	Lead and cadmium in bovine blood, low level	amp.
	Each sample is in lyophilised form equivalent to about 5.75 mL of bovine blood with additives, kept under nitrogen in rubber stoppered vials. Mass concentration in the reconstituted material	
	Analytes	
	Pb126 ± 4 μg/L Cd0.20 ± 0.05 μg/L	
ERM-CE195	Lead and cadmium in bovine blood, medium level	amp.
	Each sample is in lyophilised form equivalent to about 5.75 mL of bovine blood with additives, kept under nitrogen in rubber stoppered vials. Mass concentration in the reconstituted material	
	Analytes	
	Pb	
ERM-CE196	Lead and cadmium in bovine blood, high level	amp.
	Each sample is in lyophilised form equivalent to about 5.75 mL of bovine blood with additives, kept under nitrogen in rubber stoppered vials. Mass concentration in the reconstituted material Analytes	
	Pb	

Non-peptide hormones

Code	Product	Unit
NIST-955C	Lead in caprine blood	set (4 x 2 mL)
	This material is intended primarily for use in evaluating the accuracy of lead concentration determinations in blood and for use in validating working or secondary reference materials for lead in blood analysis. A unit consists of four vials of frozen caprine blood at four concentration levels: a base level and three progressively elevated levels that contain endogenous lead and spiked inorganic arsenic, cadmium, inorganic mercury, methylmercury, and ethylmercury. Certified values are provided for lead. Each vial contains approximately 2 mL of whole blood.	
	Certified concentration Lead (µg/dL) Lead (µmol/L)	
	Level 1 0.424 ± 0.011 0.02047 ± 0.00053 Level 2 13.950 ± 0.080 0.6733 ± 0.0038 Level 3 27.76 ± 0.16 1.3400 ± 0.0076 Level 4 45.53 ± 0.27 2.198 ± 0.013	
NIST-966	Toxic metals in blood	unit
	This material is intended for use in evaluating the accuracy of lead, cadmium and total mercury concentration determinations in whole blood. It can also be used for validating analytical methods and for providing traceability to working or secondary blood reference materials containing these constituents. It contains frozen whole bovine blood with below mentioned components at two concentration levels.	
	Analytes level 1 level 2	
	Pb	

Non-electrolyte metals in urine

NIST-2670A

Toxic elements in freeze dried urine

This material is primarily intended for use in evaluating the accuracy of clinical methods and for the calibration of apparatus used to determine the concentration of toxic metals and other elements in human urine or similar matrices. It can also be used to validate working or secondary reference materials. It consists of four bottles of freeze-dried urine, two bottles each at the low and high levels. The low level urine was prepared from human urine that was lyophilised after pooling and centrifugation. The high level urine was prepared by spiking an aliquot of the pooled and homogenized low-level urine with selected metals, followed by lyophilisation. Due to the centrifugation (which improved sample homogeneity), neither level represents a fresh urine pool from a normal human population.

Analytes	low	elevated level
Antimony	0.971 ± 0.033	0.824 ± 0.070 µg/L
Cadmium	0.0591 ± 0.0034	4.862 ± 0.084 µg/L
Cesium	1.075 ± 0.031	1.085 ± 0.052 µg/L
Cobalt	0.166 ± 0.040	51.2 ± 3.2 µg/L
lodine	88.2 ± 1.1	$88.2 \pm 1.1 \mu g/L$
Lead	0.49 ± 0.16	233.2 ± 9.4 µg/L
Mercury	0.0663 ± 0.0058	95.1 ± 0.98 µg/L
Manganese		
Molybdenum		114.1 ± 4.8 µg/L
Platinum		51.5 ± 6.6 µg/L
Selenium		229.5 ± 8.3 µg/L
Thallium	0.0162 ± 0.0045	5.417 \pm 0.064 µg/L
Thorium	0.0053 ± 0.0014	0.01606 ± 0.00077 µg/L
Uranium	0.1020 ± 0.0023	4.997 ± 0.071 µg/L

Non-peptide hormones

Code	Product	Unit
NIST-921	Cortisol (hydrocortisone) This material is intended primarily for use in the calibration and standardisation of procedures for cortisol determinations employed in clinical analysis and for routine evaluation of the daily working standards used in these procedures.	1 g
	Analyte	
	Cortisol (hydrocortisone)	
ERM-DA451	Cortisol reference serum panel of fresh frozen human sera	34 vials
	The panel is primarily intended for use in evaluation/verification of in vitro test systems for serum cortisol by method comparison with the ID-GC/MS method (for an appropriate measurement protocol, see full report). The results shall be described by linear regression/bias plot and interpreted in terms of sensitivity, specificity and metrologically correct measurement (trueness). The method comparison will also be used to investigate the suitability of the panel for recalibration of a test system. IRMM/IFCC-451 is a reference serum panel consisting of 34 vials originating from native single-donations that does not contain any additives. It is available in the form of screw capped cryo-vials (34 x 1 mL serum).	
NMIAD547	Epitestosterone °	1 mg
	The compound is supplied as a dried aliquot in a sealed ampoule and is intended for a single use to prepare a standard solution containing 0.988 \pm 0.023 mg of anhydrous epitestosterone.	
NMIAD555	19-Norandrosterone °	1 mg
	Purity (mass fraction)	
	The compound is supplied as a dried aliquot in a sealed ampoule and is intended for a single use to prepare a standard solution equivalent to 944 \pm 5 µg of 19-norandrosterone.	

set (4 x 20 mL)

Code	Product	Unit
NMIAM914	Testosterone Purity (mass fraction)	100 mg
NMIAD546	16,16,17-Testosterone-D3 ° The compound is supplied as a dried aliquot in a sealed ampoule and is intended for a single use to prepare a standard solution containing 0.999 ± 0.020 mg of anhydrous d3-testosterone. This material should be considered for use as an internal standard only	1 mg
NMIAD507	Testosterone glucuronide ° Purity (mass fraction)	1 mg
NMIAD508	Testosterone sulfate ° The compound is supplied as a dried aliquot in a sealed ampoule and is intended for a single use to prepare a standard solution 0.952 ± 0.012 mg of testosterone sulfate (NEt3	1 mg
IRMM-468	Thyroxine (T4) The material can be used as a calibrant by manufacturers and laboratories, e.g. for the preparation of lower order reference materials and for validation studies. It consists of an off-white cristalline powder in an amber glass vial sealed under N ₂ atmosphere. Each vial contains about 100 mg of the powder. Certified value (mass fraction)	vial
IRMM-469	3,3',5 Triiodothyronine (T3) The material can be used as a calibrant by manufacturers and laboratories, e.g. for the preparation of lower order reference materials and for validation studies. It consists of an off-white cristalline powder in an amber glass vial sealed under N ₂ atmosphere. Each vial contains about 100 mg of the powder. Certified value (mass fraction)	vial
Non-peptide	normones in serum	
ERM-DA192	Cortisol in human serum (unspiked) Each sample is the lyophilised form of a 1.25 mL portion of serum without additives kept under nitrogen in sealed glass ampoules. Cortisol concentration in the reconstituted material ug/l 98.8 + 2.0	amp.
	nmol/L	
ERM-DA193	Cortisol in human serum (spiked) Each sample is the lyophilised form of a 1.25 mL portion of serum without additives kept under nitrogen in sealed glass ampoules. Cortisol concentration in the reconstituted material µg/L	amp.
BCR-576	Estradiol-17-beta in human serum (low level) Each sample is the lyophilised form of a 5 mL portion of serum without additives kept under nitrogen in sealed glass ampoules. Amount-of-substance concentration in the reconstituted material	amp.
BCR-577	Estradiol-17-beta in human serum (medium level) Each sample is the lyophilised form of a 1 mL portion of serum without additives kept under nitrogen in sealed glass ampoules. Amount-of-substance concentration in the reconstituted material	amp.
BCR-578	Estradiol-17-beta in human serum (high level) Each sample is the lyophilised form of a 1 mL portion of serum without additives kept under nitrogen in sealed glass ampoules. Amount-of-substance concentration in the reconstituted material	amp.
ERM-DA347	Progesterone in human serum (low) Each sample is the lyophilised form of a 1 mL portion of serum, containing endogenous progesterone, without additives kept under nitrogen gas in sealed glass ampoules. Progesterone concentration in the reconstituted material3.19 ± 0.07 ng/L 10.13 ± 0.21 nmol/L	amp.
BCR-348R	Progesterone in human serum (high) This material is intended to be used for trueness assessment and quality control of progesterone measurement procedures using ID-GC-MS and to verify the comparability of results from different laboratories using that technique. It can also be used for calibration or quality control of in vitro diagnostic devices if commutability of this material has been demonstrated using ID-GC-MS reference method for comparison. It consists of 1 mL of human serum lyophilised in an ampoule which is sealed under N2 atmosphere. Each ampoule contains about 80 mg of the lyophilised powder. Mass concentration: 8.5 ± 0.4 µg/L	amp.

Proteins

Code	Product	Unit
ERM-DA345A	Testosterone in human serum	vial
	This material is intended for method validation and for monitoring the performance of methods commonly used in medical laboratories. ERM-DA345A was prepared from a single native female human serum pool, part of which was spiked with testosterone in methanol to produce a material with a level of testosterone within the normal male range. The material was sterile filtered and sub-sampled into plastic screw-cap 3 mL vials. Each vial contains a minimum of 0.8 mL. The certified value (mass fraction) is based on isotope dilution mass spectrometry.	
	Certified value 5.58 ± 0.20 μg/kg	
ERM-DA346A	Testosterone in human serum	vial
	This material is intended for method validation and for monitoring the performance of methods commonly used in medical laboratories. ERM-DA346A was prepared from a single native female human serum pool. The material was sterile filtered and sub-sampled into plastic screw-cap 3 mL vials. Each vial contains a minimum of 0.8 mL. The certified value (mass fraction) is based on isotope dilution mass spectrometry.	
	Certified value 0.25 ± 0.04 µg/kg	

Proteins

Code	Product	Unit
BCR-486	Alphafoetoprotein (AFP), human purified	amp.
	Each sample is in the lyophilised form and it contains purified AFP without additives. The material is kept under nitrogen gas in sealed glass ampoules. The protein mass per ampoule is equivalent to 100 ± 9 µg when the material is reconstituted. Carbohydrate mass of the molecule is not included.	
	Protein mass per ampoule 100 \pm 9 μ g	
BCR-393	Apolipoprotein AI, human	amp.
	Each sample is in the lyophilised form of a 1.5 mL portion of Apo AI solution without additives. The material is kept under nitrogen gas in sealed glass ampoules.	
	Mass concentration in the reconstituted material 1.06 \pm 0.05 g/L	
BCR-394	Apolipoprotein All, human	amp.
	Each sample is in the lyophilised form of a 1.5 mL portion of Apo A II solution without additives. The material is kept under nitrogen gas in sealed glass ampoules.	
	Mass concentration in the reconstituted material	
ME 30830	CDT (SDT) in Human Serum Medisafe CDT AMF 1/01-A S-plus	10 x 0.5 mL
	Negative control from non-abuser	
	This material is no longer available	
ME 30840	CDT (SDT) in Human Serum Medisafe CDT AMF 1/01-B S-plus	10 x 0.5 mL
	Positive control from alcohol-abuser	
	This material is no longer available	
HEC JDS2	HbA1c in haemoglobin in buffer	unit
	JDS HbA1c Lot 2 is primarily intended for use in the calibration and standardization of procedures for measurement of Haemoglobin A1c in clinical specimens. It can also be used for validating working or secondary reference materials. The material consists of a lysed solution (carbonate buffer) of erythrocytes originating from human whole blood. The material is free from plasma components and without stabilisers. A single set of JDS HbA1c Lot 2 consists of five vials (0.1 mL) with concentrations levels 4-13%. Certified values:	
	Level HbA1c (%)	
	14.04±0.08	
	25.38±0.05	
	4	
	512.63±0.13	
BCR-613	Prostate specific antigen (PSA)	amp.
	Each sample is in lyophilised form and it contains purified PSA without additives. The material is kept under argon gas in sealed glass ampoules. Carbohydrate mass of the molecule not included. Prostate specific antigen in the reconstituted material	
	Mass concentration	
BCR-457	Thyroglobulin (Tg), human	amp.
	Each sample is in lyophylised form and equivalent to about 100 μl of purified Tg without additives. The material is kept under nitrogen in sealed glass ampoules.	·
	Mass concentration in the reconstituted material0.324 \pm 0.018 g/L	

Code	Product		Linit	
Proteins in blo	od		0111	
	Haamiglahingyanida (HiCN) in baying blood l	vento	0000	
BCK-522	Haemiglobincyanide (HICN) in bovine blood i Each sample is in the form of bovine blood lysate and a haemiglobincyanide with a volume of 10 mL. The mater ampoules. Molar mass and molar extinction coefficient been shown to be equivalent. Absorbance at 540 nm HiCN 0.5457 ± 0.0009 Concentration HiCN (Fe) 800.3 ±1.3 mg/L HiCN (Fe) 49.61 ± 0.08 µmol/L	ysate mass concentration of about 800.3 mg/L rial is kept in sealed brown neutral borosilicate glass of bovine haemoglobin and human haemoglobin have	amp.	
Proteins in ser	rum			
ERM-DA470	15 Plasma proteins in human serum		amp.	
	Each sample is the lyophilised form of a 1.0 mL portion aprotinin). The material is kept under nitrogen gas in the Chlorbutylcaoutchouc GT rubber stoppers and PP scree sample is below 0.008 g/g.	of serum with additives (sodium azide and readed glass bottles with w caps. The water mass fraction of the		
	Analyte mass concentration in g/L	Analyte mass concentration in g/L		
	$\begin{array}{llllllllllllllllllllllllllllllllllll$	Transferrin (TF) 2.45 ± 0.06 Complement C3c (C3c) 1.091 ± 0.027 Complement C4 (C4) 0.151 ± 0.005 C-reactive protein (CRP) 0.0392 ± 0.0019 Immunoglobulin G (IgG) 9.68 ± 0.10 Immunoglobulin A (IgA) 1.96 ± 0.04 Immunoglobulin M (IgM) 0.797 ± 0.023		
	This material is no longer available. It has been replaced by ERM-DA470k/IFCC			
ERM-DA470k/IFCC	Proteins in human serum The ERM-DA470 in combination with special value tran assigned to the new material. Initially, certified values w A2M, AAG, AAT, ALB, C3c, C4, HPT, IgA, IgG, IgM, TF Information about other components may become avail	sfer procedures constitute the basis for the values ill be provided for twelve proteins: RF, and TTR. able later.	amp.	
	Each sample is the lyophilised form of a 1.0 mL portion 1-piperazineethanesulfonic acid (HEPES), sodium azid under nitrogen gas in threaded glass bottles with rubbe material has to be reconstituted with (1.00 ± 0.01) mL o in blood collection centres according to a procedure en- was processed in five batches, pooled, spiked with B2N screw caps. The serum was lyophilised in the vials and spectrophotometry in different commercial platform/rea- concentrations.	of serum with additives (4-(2-hydroxyethyl)- e, bezamidine chloride and aprotinin). The material is kept r stoppers and polypropylene screw caps. The lyophilised f distilled water. Serum was produced from blood collected suring healthy donors, and low lipid content. The serum A and CRP, and filled into vials (1 mL serum per vial) with stored at -70 °C. Nephelometry, turbidimetry or gent combinations were used to measure protein		
	This reference material has replaced ERM-DA470			
NIST-2921	Human cardiac Troponin complex		5 x 115 µL	
	This material is primarily intended for use in calibrating cardiac troponin I (cTnl) in human serum. It can also be materials. A unit of consists of five vials, each containin cardiac troponin complex.	clinical procedures and devices for the determination of used for value-assignment of calibrators and control g approximately 115 µL of a dilute solution of human		
	cTnI			
Proteins in oth	ner matrices			
BCR-405	Glycated haemoglobin (HbAlc) in human hae Each sample is in lyophilised form and equivalent to ab erythrocytes without preservatives. The material is kept HbA _{1C} in reconstituted material	molysate (RM) out 0.5 mL of a solution of haemolysate of human under carbon monoxide in sealed glass ampoules.	amp.	
Vitamins and r	nicronutrients			
			0.01 (/)	
1919-970	This material is intended primarily for use in validating r similar matrices. It can also be used for quality assuran unit consists of four ampoules of frozen human serum, (low normal). Each ampoule contains approximately 2. g/L (10 % mass concentration) aqueous metaphosphor preserve the ascorbic acid.	nethods for determine ascorbic acid in human serum and ce when assigning values to in-house control materials. A two ampoules each of level I (high normal) and level II 2 mL of solution, a 1:1 mixture of human serum and 100 ic acid (MPA). The MPA is present to stabilize and	Set (4)	
	Certified concentration values for total ascorbic acid (TA	AA) (ascorbic acid + dehydroascorbic acid).		
	Lovels value	95 % confidence		

Levels	value	95 % confidence
level I, µmol/L of solution	8.41	7.75 to 9.07
level II, µmol/L of solution	28.05	27.56 to 28.54

Others

Code	Product	Unit
NIBSC73/515	anti-D (Rho) Antibodies, Human The 2nd British Standard for Anti-D (Rho) Antibodies consists of ampoules containing the freeze-dried residue of approximately 0.5 mL of pooled human defibrinated plasma. Each ampoule of the Standard contains 11.5 International Units of anti-D antibody. This Standard replaces the 1st British Standard for Anti-D (Rho) Antibodies (72/229) but was derived from the same plasma pool. The Standard is intended for use in the assay of plasma anti-D levels by automated haemagglutination	
NIBSC84/628	anti-c Serum, Human The British Standard for anti-c consists of ampoules containing the freeze-dried residue of approximately 1 mL of pooled defibrinated human plasma without preservative. The preparation has been calibrated by automated haemagglutination methodology (AutoAnalyzer) against the International Standard for Anti-c Incomplete Blood Typing Serum, Human, 67/160. Each ampoule contains 13 International Units of Anti-c. The preparation is intended for use as a working reference preparation for the quantitation of Anti-c by automated haemagglutination (AutoAnalyzer). Such assays may be carried out, for example, for monitoring maternal antibody levels during and after pregnancy.	amp.
NIBSC02/282	Negative Control for FCXM This standard consists of vials containing the freeze-dried residue of approximately 1.0 mL of pooled normal human AB+ serum. This standard is intended for use as a negative control for flow cytometry cross matching (FCXM). It is not intended for use in calibration of individual laboratory standards	amp.

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Reference materials catalogues

Pharmaceutical reference substances and impurities 2008

Reference substances from the world's Pharmacopoeia: United States Pharmacopoeia, European Pharmacopoeia, British Pharmacopoeia, International Pharmacopeia, Pharmacopée Française,Pharmacopoeia Helvetica. Certified pharmaceutical impurities plus over 2,200 impurity standards from LGC Luckenwalde.



Reference materials for physical properties 2008 / 2009

This catalogue lists a comprehensive range of reference materials and standards covering many physical properties including thermal, surface properties, particle shape and size, ion activity, viscosity, electrical, and polymeric properties. Also featured are melting point standards and standards for the use with differential scanning calorimety (DSC).



Phytochemical reference standards 2008

2500 phytochemical reference standards from ChromaDex (primary, secondary and reagent grade) for herbal supplements, nutraceuticals and functional foods. Full range of standards from Artichoke through to Valerian and Vitamins, including user friendly kits for most common analyses.

Metals and related products reference materials catalogue 2008

The catalogue for Metals and related materials presents a listing of reference materials grouped according to their matrix type and further subdivided by their chemistry. Listings give information on each product such as composition, weight of sample and format.



Reference materials for clinical, forensic and sports drugs applications 2008 / 2009

Sports drugs: Pure steroids, growth promotants, stimulants, metabolites Clinical analysis: Blood, serum, urine with certified values of trace elements, proteins and vitamins. Forensic analysis: Alcohol and drugs in blood, serum, urine and hair; deuterated and native forensic standard solutions.

ATCC cell biology catalogue

This catalogue contains a complete listing of 3,600 individual cell lines and hybridomas by name, species, tissue, disease, and application and is designed to be used with the ATCC online catalogue where detailed cell line information may be found.



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Analytical reference materials, standards and high purity solvents 2008 / 2009

Matrix reference materials for environmental, food and industrial applications. Reference standards for organic contaminants, food additives, mycotoxins, veterinary medicines and pharmaceuticals. Stable isotope labelled contaminant standards. Inorganic standards for AA/ICP and ion chromatography. Physical property standards and high purity solvents.



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