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IMEP®

IRMM
Isotope Measurements Unit

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The International Measurement Evaluation Programme

IMEP-17
Trace and Minor Constituents in Human Serum
EUR 20657 EN
Report to Participants

Part 1: International comparability

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The Mission of IRMM is to promote a common European measurement system in support of EU policies, especially internal market, environment, health and consumer protection standards

IMEP®

provides certified values with demonstrated traceability and demonstrated uncertainty, independent of the participants' results

enables result-oriented rather than procedure oriented evaluation of performance

demonstrates a degree of equivalence in measurement results on an international scene

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1. Introduction to IMEP

The International Measurement Evaluation Programme (IMEP) is a programme for interlaboratory comparisons. It is founded, owned and co-ordinated by the European Commission's Institute for Reference Materials and Measurements (IRMM) [1]. The programme was established in 1988, in order to shed light on actual state of the practice in chemical amount measurements. Two facts made the programme known around the world. Firstly, it was one of the few interlaboratory comparison programmes worldwide that was not based on consensus values derived from the participants' results. Secondly, contrary to common belief, the results of the various IMEP comparisons showed an unexpected large spread of participants' results for simple measurement problems.

IMEP is a metrological tool with which routine laboratories can compare objectively their results against certified values. It is open to all laboratories and guarantees confidentiality with respect to the link between results and the participants' identity. Certified Test Samples (CTS) with undisclosed values are sent to interested participants, who are asked to return their results together with uncertainty statements. The certified values are based on primary [2] or other internationally recognised measurement procedures applied by one or more experienced reference measurement laboratories (RMLs). The underlying philosophy is that the best possible values, which will serve as reference points in IMEP, are obtained from well understood measurement processes rather than via a mere consensus approach.

IMEP aims to help build up confidence where trade or border crossing problems exists (between European countries or between Europe and elsewhere). Moreover, IMEP runs in support of European Commission (EC) policies (e.g. Consumer Protection and Public Health, Single Market, Environment, Research and Technology, External Trade and Economic Policy) and supports the chemical measurement systems of the European Union (EU) member states and pre-accession countries by providing assistance to the development of the national measurement systems.

Since 1988, IMEP has focused mainly on trace analysis in matrices, such as water, polyethylene, sediment, carbon dioxide, rice, car catalysts and serum [3, 4, 5]. In July 1999 IRMM launched the IMEP-17, which focuses on twenty components in two human serum materials. The organisation of the interlaboratory comparison and the participants' results for serum Material 1 are the focus of this report.

2. IMEP-17

2.1. Background and objectives

The initial planning of IMEP-17 took place during the second half of 1999. The initiative came from members of EQALM* who stressed the need for more reference measurement procedure values to support routine quality assurance (QA) work, e.g. in external quality assessment (EQA) schemes and reference materials (RM) production. The project has been organised in close collaboration with the C-AQ IFCC† and members of EQALM. IMEP-17 aims to assist the

* European committee for external quality assurance programmes in laboratory medicine.

† Committee for analytical quality of the international federation for clinical chemistry and laboratory medicine.

clinical community to evaluate the degree of international comparability for selected measurements in serum. This is also in support of the EC directive 98/79/EC [6] and EU member states' legislation, e.g. [7].

2.2. Choice of components and measurands

The following twenty elements and organic components were selected for IMEP-17:

- Calcium (Ca), chloride (Cl), copper (Cu), iron (Fe), potassium (K), lithium (Li), magnesium (Mg), sodium (Na), selenium (Se) and zinc (Zn),
- Glucose, cholesterol, creatinine, urea, uric acid, thyroxine (T4), albumin, immunoglobuline G (IgG), amylase and γ-glutamyl transferase (γ-GT)).

The selection was based on recommendations from the C-AQ IFCC, the needs of routine laboratories, and on the capability of National Metrology Institutes (NMIs) and Reference Measurement Laboratories (RMLs) to provide reference measurement procedure values of the highest quality.

The measurands, i.e. the quantities subject to measurement [8] are the total amount-of-substance concentration, mass concentration or catalytic activity concentration of the components in the respective serum material. Results are presented in the units that the Finnish EQA organisation Labquality uses in its clinical chemistry surveys [9].

2.3. Special educational aspect

There are many examples where measurement results need to be compared. Proper conclusions require that the end-user has some indication of the quality of the results. Statements of precision and/or trueness are often used for this purpose. New standards request that laboratories evaluate and report the quality of their measurements in greater detail than before [10, 11]. An internationally agreed general approach on how to evaluate and report the quality of a measurement result is outlined in an ISO document [12]. The recommended term for the quality statement is 'uncertainty'.

Despite a decade's work, there is still considerable confusion in many chemistry laboratories on how available quality information is best combined into an uncertainty statement. Initially, much emphasis was on the part of the evaluation where the measurement is described with a mathematical model. More recently, however, examples try to illustrate how existing overall validation and quality control data can be used [13]. In 2002, ILAC* published recommendations on how uncertainty should be introduced taking into account present state-of-the-art understanding [14].

The C-AQ IFCC proposed that the uncertainty concept be the focus of a special educational aspect of IMEP-17. A report with two examples was prepared [15]. It depicted typical measurements in a hospital laboratory with automated instrumentation. The report was made available to all participants in IMEP-17 and can be downloaded from the Internet [1].

* International laboratory accreditation cooperation.

3. Production of the certified test samples

3.1. Serum materials

3.1.1. Production

The production and initial characterisation of the serum materials were performed during 2000 under the responsibility of A. Uldall. DEKS[*] Herlev University Hospital and SSI[†] (Denmark) prepared two test materials from pools (~20 litres) of fresh human serum [16, 17, 18]. The original blood was collected from healthy patients at Hjørring County Hospital following WHO recommendations. Each individual donor, as well as the final pools, were tested and found negative for HIV, Hepatitis B and Hepatitis C.

Material 1 was left unmodified to resemble a normal patient serum. Material 2 was prepared by spiking the serum pool and mixing it in a bottle with plenty of free space. In the spiking process, pure compounds and reagents were used (de-ionised water, hydrochloric acid, potassium hydroxide, creatinine, glucose, glycerol, lithium chloride, magnesium chloride hexa-hydrate, potassium chloride, urea, uric acid dissolved in 0,02M KOH, zinc chloride, amylase[‡] and γ-GT) from bovine kidney.[§] The spiking was intended to achieve higher but still clinically relevant concentrations.

Each pool was carefully mixed and sterile-filtered (0,22 µm) before transferring approximately 9,5 mL of serum into each of 2 200 polypropylene vials. The vials were closed with a Teflon-coated stopper and an outer metal seal, and stored at -80 °C.

3.1.2. Homogeneity and stability checks

The homogeneity of the respective serum was assessed by determining the concentrations of seven components in 42 vials (Material 1) and 30 vials (Material 2). The conclusion from that assessment was that the materials were fit for their intended use. Further support to this conclusion was obtained during the certification campaign.

Studies by DEKS indicate that liquid sera in frozen state are stable for several months (at ≤ -20 °C) to many years (at ≤ -80 °C). The stability under higher temperature conditions was assessed by storing vials of Material 2 at 4 °C, room temperature, 30 °C and 37 °C. The concentrations of seventeen components were determined at five occasions over a period of one month and compared with those found in vials stored at -80 °C. All components, except amylase from 30 °C and glucose at 37 °C, were stable at all temperatures over the period [19]. The two materials have also been subject to a long-term stability study (one year) at -80 °C and -135 °C.

[*] Danish Institute for External Quality Assurance for Laboratories in the Health Care.

[†] Statens Seruminstitut (SSI).

[‡] EC number 3.2.1.1 from human saliva, 500 U (25 °C), cat. No. 10092 ('BioChemica' purity, 100 U/mg), Sigma Aldrich.

[§] γ-GT, EC number 2.3.2.2 from bovine kidney, 500 U (25 °C), cat. No., G4756 (grade 2 purity; 26 U/mg) from Sigma-Aldrich.

3.1.3. Density and pH

The density at 22 °C for both materials is 1,023 ± 0,002 $kg \cdot L^{-1}$. The pH of Material 1 is 7,52. The pH of Material 2 is 7,77, which is usual for serum where CO_2 has escaped. The higher than normal pH is known to have an effect on result with Ortho Vitros' measuring systems in that albumin is somewhat elevated and urea lowered [20]. The IMEP-17 participants were informed about this interference and could where possible, choose other methods. Further details about method performance will be provided in Part 2 of this report [21].

3.2. Reference measurement laboratories

3.2.1. Contributing institutes

Following an invitation (autumn 2000), reference measurement laboratories (RMLs) at twelve institutes (Table 1) expressed interest to participate in the certification campaign coordinated by IRMM. The institutes have experience and a proven successful record in specific applications of primary or other internationally approved reference measurement procedures. After an evaluation of the institutes' existing methodology related to the IMEP-17 components, 69 assignments were distributed. The objective was to obtain two or three independent reference measurement procedure values for each component. The RMLs carried out their work during 2001.

Table 1. Institutes contributing to the certification work in IMEP-17.

Institute and location	Country
DGKC Deutsche Gesellschaft für Klinische Chemie e. V. – Bonn	Germany
DGKC Deutsche Gesellschaft für Klinische Chemie e. V. – Hannover	Germany
IRMM Institute for Reference Materials and Measurements - Geel	European Commission
NRCCRM National Research Centre for Certified Reference Materials - Beijing	China
KRISS Korean Research Institute of Standards and Science - Yusung Taejon	South Korea
PTB Physikalisch-Technische Bundesanstalt – Braunschweig	Germany
LGC Laboratory of the Government Chemist - Teddington	United Kingdom
ETH Eidgenössische Technische Hochschule - Zürich	Switzerland
BAM Bundesanstalt für Materialforschung und –Prüfung – Berlin	Germany
NIST National Institute of Standards and Technology - Gaithersburg	USA
EMPA Swiss Federal Laboratories for Materials Testing and Research - St Gallen	Switzerland
SP SP Swedish National Testing and Research Institute - Borås	Sweden

3.2.2. Methodology

Table 2 contains an overview of the methods applied by the RMLs. Most of the methods require special instrumentation and calibrators. The work is time consuming and therefore expensive. These methods do, however, have advantages. When applied to their extreme, they provide traceability to SI, or to calibrators or procedures of higher metrological order. The uncertainties of the results are then also the lowest attainable. Detailed information concerning the reference measurements is available in the certification report [22].

Table 2. Overview of the methods applied by the reference measurement laboratories in IMEP-17. Special links in the traceability chains are indicated for some components.

Component	Applied isotope-specific measurement methods*	Other applied measurement method(s)†	Special link in traceability chain
Ca	ID-ICP-MS, ID-TIMS		
Cl	ID-ICP-MS	Coulometry, titrimetry	
Cu	ID-ICP-MS, ID-TIMS		
Fe	ID-TIMS		
K	ID-ICP-MS	FAES, ion chromatography	
Li	ID-ICP-MS, ID-TIMS	Ion chromatography	
Mg	ID-ICP-MS	Ion chromatography	
Na		Gravimetry, FAES	
Se	ID-ICP-MS	NAA	
Zn	ID-ICP-MS, ID-TIMS		
Glucose	ID-GCMS		
Cholesterol	ID-GCMS, ID-LCMS		
Creatinine	ID-GCMS, ID-LCMS		
Urea	ID-GC-MS		
Uric acid	ID-GC-MS		
Thyroxine (T4)	ID-LC-MS		
Albumin		RID	BCR-470 [23]
IgG		RID	BCR-470 [23]
Amylase		Enzymatic	IFCC C-RSE primary reference procedure, 37 °C [24]
γ-GT		Enzymatic	IFCC C-RSE primary reference procedure, 37 °C [24]

3.2.3. The international measurement infrastructure - Traceability and comparability

An international infrastructure has been created to deal with fundamental aspects of measurement (Figure 1). A core activity is the maintenance and development of the SI system with its base quantities and units. This is done by the responsible bodies CGPM, CIPM and BIPM, in collaboration with international organisations and national metrology institutes (NMIs).

* ID= isotope dilution, ICP = inductively coupled plasma, MS = mass spectrometry, TI = Thermal ionisation, LC = liquid chromatography, GC = gas chromatography.
† FAES = flame atomic emission spectrometry, NAA = neutron activation analysis, RID = radial immunodiffusion.

The institutes contributing to the certification campaign in IMEP-17 (Table 1) are NMIs or reference measurement laboratories (RMLs). They support routine laboratories in their country with expert advice and calibration services, and may have a stated responsibility to assure that measurements are traceable. A 'traceability chain' (Figure 2) is useful to illustrate how values obtained by measurement procedures and those assigned to calibrators are linked together [25]. There exists methodology for the twenty components in IMEP-17 that enable the participants' results (routine level) to be traceable to the SI (Table 2). A prerequisite, however, is that participants and manufacturers clearly can describe which calibrators and procedures they use. If this information is missing, proper conclusions about the traceability of the participants' results cannot be drawn. As a consequence, it may not be meaningful to compare results obtained by different laboratories.

Recently a 'mutual recognition arrangement' (MRA) has come into operation [26]. The MRA (see Figure 1) enables NMIs and RMLs to demonstrate their measurement capability by participating in special interlaboratory comparisons, so-called key comparisons. This can be seen as 'proficiency testing' or EQA at the highest level. There are links between such comparisons and the certified values for Ca, glucose, creatinine and cholesterol in IMEP-17 [27, 28, 29, 30, 31].

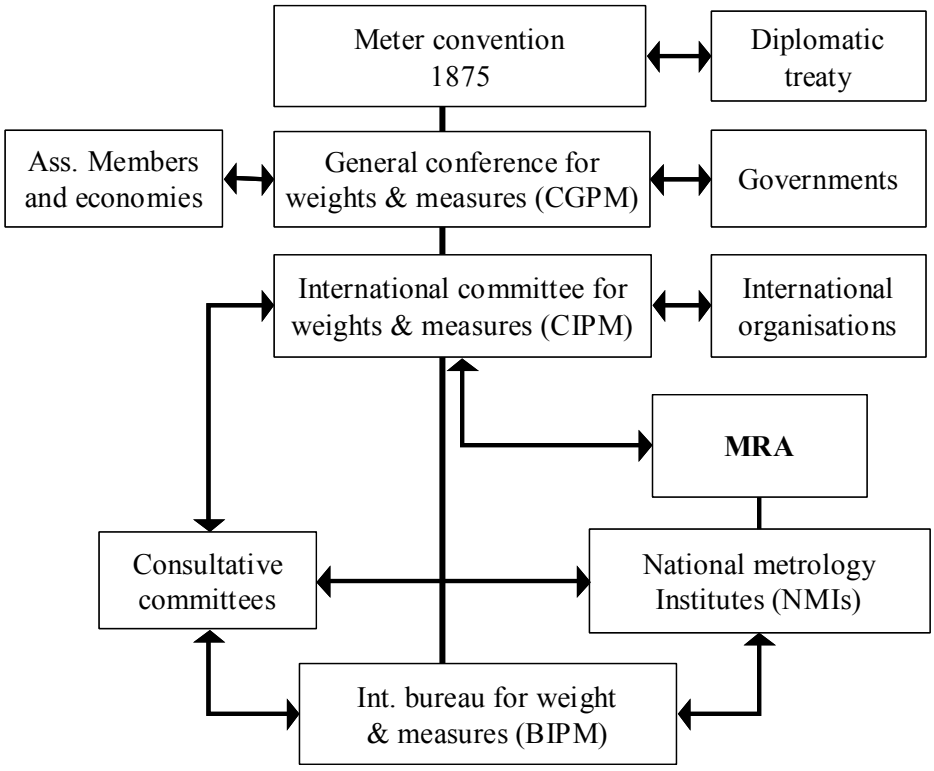


Figure 1. Overview of the international measurement infrastructure. As part of the 'Mutual recognition arrangement' (MRA) [2], national metrology institutes demonstrate their capability by participating in special interlaboratory comparisons ('key comparisons').

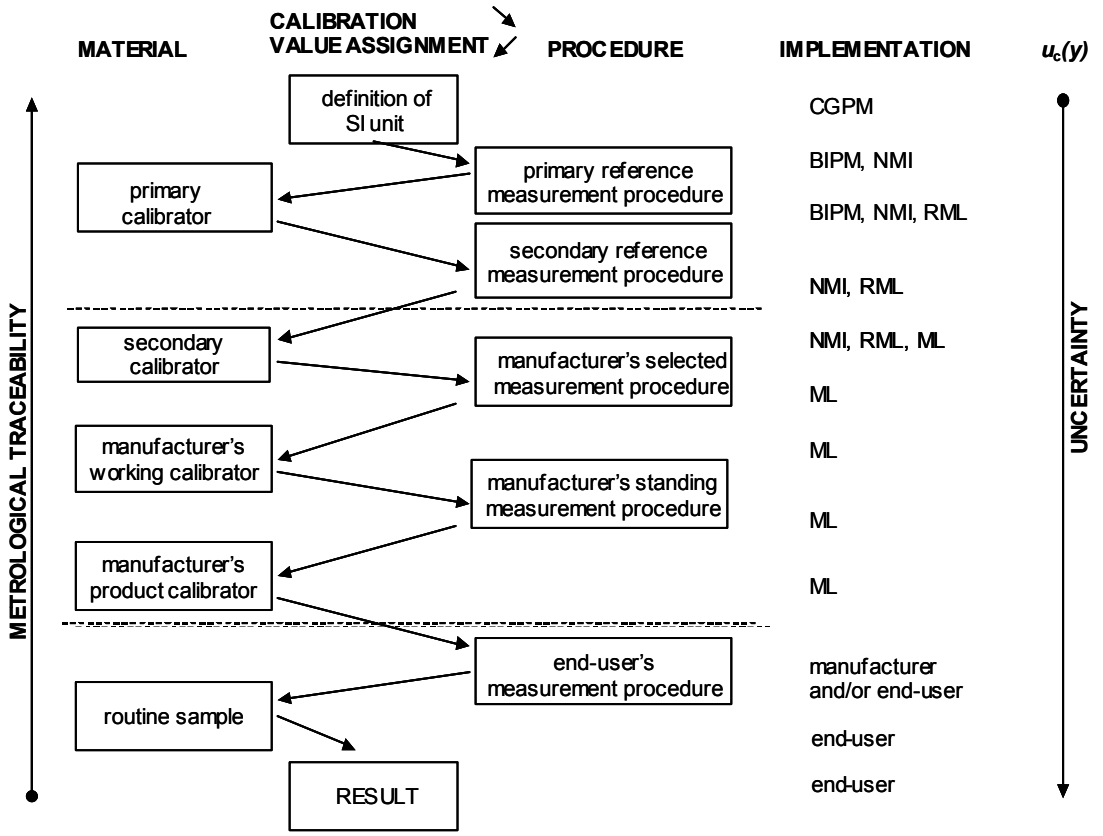


Figure 2. The certified values for the IMEP-17 materials are traceable to measurement standards of higher metrological order (reference points above the upper dotted line) [25]. The participant (end-user) normally uses a procedure developed by a commercial manufacturer (reference point under lower dotted line). The manufacturers must clearly describe which calibrators and procedures (reference points between dotted lines) they used when they developed the end-users' measuring systems. If this information is missing, proper conclusions about the traceability of the participants' results cannot be drawn. As a consequence, it may not be meaningful to compare results obtained by different laboratories.

3.3. Assignment of property values – The certification process

3.3.1. Basic criteria

The fact that an institute, which performs reference measurements for the IMEP, has a certain status or applies special methodology is, in itself, not sufficient. The institutes must provide detailed information about their experimental work. Such documentation is necessary in order to create confidence in the certified values. The reference measurement laboratories (RMLs) are requested to enclose an uncertainty statement according to the GUM [12] supported by an uncertainty budget. The RMLs may also refer to other documents, e.g. publications, results from high-level interlaboratory comparisons, and method validation studies to support their claims.

Failure of providing sufficient information, entitles IRMM to exclude data when calculating the certified value. In case there is not enough supportive information to establish a certified value for a specific component, this component may be excluded from the certificate, or the certificate will clearly indicate that the numbers given are for information.

3.3.2. Discussion and re-examination of submitted data

When two or more institutes report a reference measurement procedure value, the starting point for the evaluation was that the values should agree within the respective stated expanded uncertainties. If this is not the case, the RMLs are notified and asked to check calculations and report back. To be fit for purpose, the uncertainty of each reference measurement procedure value must be significantly smaller (preferably by a factor of 5 to 10) than the expected range of the participants' results (routine level).

An 'IMEP-17 reference value' is then calculated for each component. The average of the accepted reference measurement procedure values is normally taken as the estimate of the value of the measurand. The associated uncertainty is calculated by combining the individually reported uncertainties. In case reference measurement procedure values do not agree within their stated expanded uncertainties, an additional contribution is added that just covers the between-laboratory variation. All calculations were done using the software GUM Workbench [32].

3.4. Certified values

Based on the IMEP-17 reference values, the IRMM issued certificates for the two serum materials [33, 34]. Each material is then referred to as a 'certified test sample'. Because they are produced for a specific purpose (an IMEP comparison) they are not labelled, provided or referred to as 'certified reference materials'.

Certified reference values were established for 19 components in Material 1 (Table 3) and 11 components in Material 2 (Table 4). The associated uncertainties are expressed as expanded uncertainties (U) with a coverage factor (k) equal to 2. Copies of the certificates are available from the IMEP homepage [1].

Table 3. IMEP-17 certified values for serum material 1, expressed as amount-of-substance concentration, mass concentrations or catalytic activity concentration. For amylase and γ-GT, the coverage factor, *k*, required to obtain an interval with a level of confidence of ~95% is 2,8.

Component	***Unit***	***Certified value***	**Expanded uncertainty *U*, *k*=2**
Ca	mmol/L	2,334 2	0,006 9
Cl	mmol/L	102,9	1,1
Cu	µmol/L	17,57	0,10
Fe	µmol/L	19,39	0,54
K	mmol/L	3,735	0,021
Mg	mmol/L	0,812 3	0,005 6
Na	mmol/L	140,36	0,95
Se	µmol/L	1,022	0,035
Zn	µmol/L	16,32	0,35
Glucose	mmol/L	4,412	0,033
Cholesterol	mmol/L	5,111	0,021
Creatinine	µmol/L	74,57	0,57
Urea	mmol/L	4,772	0,049
Uric acid	µmol/L	308,9	5,7
Thyroxine (T4)	nmol/L	97,6	1,3
Albumin	g/L	41,5	2,7
IgG	g/L	10,47	0,48
Amylase	U/L	56,8	2,6
γ-GT	U/L	34,70	0,93

Table 4. IMEP-17 certified values for serum material 2, expressed as amount-of-substance concentration or catalytic activity concentration. For amylase and γ-GT, the coverage factor, *k*, required to obtain an interval with a level of confidence of ~95% is 2,8.

Component	*Unit*	*Certified value*	*Expanded uncertainty U, k=2*
Cu	µmol/L	16,48	0,12
K	mmol/L	5,727	0,031
Mg	mmol/L	1,318	0,010
Zn	µmol/L	29,38	0,29
Li	mmol/L	0,904 9	0,007 4
Glucose	mmol/L	8,41	0,18
Creatinine	µmol/L	168,8	1,3
Urea	mmol/L	10,08	0,13
Uric acid	µmol/L	542	16
Amylase	U/L	88,4	3,9
γ-GT	U/L	72,7	1,9

3.5. Use of remaining samples

There remain some 500 vials of each test material. These are offered free of charge (shipping costs will be invoiced) to NMIs, EQA scheme organisers and medical laboratories in support of method development and validation work. A simple application form will be placed on www.imep.ws.

4. Participant coordination

4.1. Regional coordinators

IMEP uses 'regional coordinators' with defined roles and responsibilities. They seek for participants in their region, distribute the samples and any information available, and act as the local contact point in case of problems. The coordinators are often people at institutions, which are directly involved in the measurement infrastructure of their country or region.

Candidate coordinators were contacted beginning of December 2001. The invitations were primarily sent to representatives of national EQA organisations, or other clinical experts. Where such contacts could not be established, staff at national metrology institutes (e.g. Rumania) or accreditation bodies (e.g. Turkey) was approached. In U.S.A. the coordinator, made further contacts with the profession to find out the best approach for the survey. The 36 regional co-ordinators for IMEP-17 are listed in Table 5. Full address information is available on the IMEP homepage [1].

Table 5. Regional co-ordinators for IMEP-17.

Coordinator and institute / organisation	Country / region	Coordinator and institute / organisation	Country / region
Dr. A. Bulo Univ. Hospital Center Mother Teresa, Tirana	Albania	Dr. M. L. Castillo de Sanchez Assoc. Mex. de Bioquím. Clín., Col. del Valle	Mexico
Dr. D. Mazziotta FBA, La Plata	Argentina	Mrs. H. Steensland NKK, Oslo	Norway
Dr. L. A. Penberthy RCPA-AACB QA Progr. Ltd., Adelaide	Australia New Zealand	Dr. Z. Wang Nat. Centre for Clin. Lab – CNQAS, Beijing	P.R. China
Prof. M. M. Müller Kaiser Franz Josef-Spital, Vienna	Austria	Mr. A. Brzezinski Polish Centre for Quality Assessment, Lodz	Poland
Dr. J.-C. Libeer Sci. Inst. of Public Health, Brussels	Belgium	Dr. M. Wróblewska Polish College of Lab. Medicine., Gdansk	
Prof. K. Tzatchev Medical University, Sofia	Bulgaria	Mrs. M.-A. Peca-Gomes Inst. Nacional de Saude, Lissabon	Portugal
Dr. J. Gun-Munro QMP-LS, Toronto	Canada	Dr. S. Duta National Institute of Metrology, Bucharest	Rumania
Dr. D. Juretic University of Zagreb, Zagreb	Croatia	Dr. J. Balla J.A. Reiman Hospital, Presov	Slovakia
Dr. E. Ziras CACCLM, Nicosia	Cyprus	Dr. S. Bratoz Medical Centre Ljubljana, Ljubljana	Slovenia
Mr. M. Budina SEKK, Pardubice	Czech Republic	Mr. J. C. McCulloch Thistle QA, Johannesburg	South africa
Dr. A. Uldall DEKS, Herlev	Denmark	Mrs. C. Ricós Hospital General Vall d'Hebron, Barcelona	Spain
Mrs. M. Loikkanen Labquality, Helsinki	Estonia Finland	Dr. G. Nordin EQUALIS AB, Uppsala	Sweden
Dr. R. Kruse DGKC, Bonn	Germany	Dr. H. Baadenhuijsen SKZL, Nijmegen	The Netherlands
Mrs. Z. Nagyné Szilágyi National Office of Measures, Budapest	Hungary	Mr. P. Yýldýzlar Turkish Accreditation Agency, Ankara	Turkey
Dr. E. Olafsdottir Landspitali Univ. Hospital, Reykjavik	Iceland	Dr. D. Bullock UK NEQAS, Birmingham	United Kingdom
Dr. D. Harell Rabin Medical Center, Petach-Tikva	Israel	Mr. D. Tholen Statistical Consulting Services, Traverse City Mrs. Sue Empson American Proficiency Institute, Traverse City	USA
Dr. A. Menditto, Mrs. M. Patriarca Inst. Superiore di Sanitá, Rome	Italy	Dr. S. Ignjatovic Clinical Centre of Serbia, Belgrade	Yugoslavia

4.2. *Information to regional coordinators and participants*

With the invitation, the candidate regional coordinators received a detailed information package for IMEP-17 (Annex 2). It consisted of five parts:

- An invitation letter to candidate regional coordinators explaining the background and objectives of the IMEP-17 project,
- A list of tasks and guidelines for regional co-ordinators,
- A reply form for invited candidate regional coordinators,
- Reference to examples of uncertainty evaluation for routine clinical chemistry,
- A combined questionnaire and results report form outlined in Microsoft Excel.

All documents were distributed in paper and electronic form. Coordinators were encouraged to translate the necessary information into their native language if necessary (except for the report form, Section 4.2.1).

4.2.1. The combined electronic questionnaire and results report form

A four-sheet report form in Excel was designed to handle the participants' data. The report form was based on a template developed by G. Nordin (EQUALIS). Sheet 1 asked for address details and for information to gain more insight into the laboratories' normal work. Sheet 2 was foreseen for information about the participants' measuring systems. This sheet used, to a large extent, drop-down menus linked to tables with comprehensive information about available methods, instruments and calibrators (Figure 3). The information was provided by Labquality [9]. In sheets 3-4 the results from measurements on Material 1 and 2 respectively could be entered.

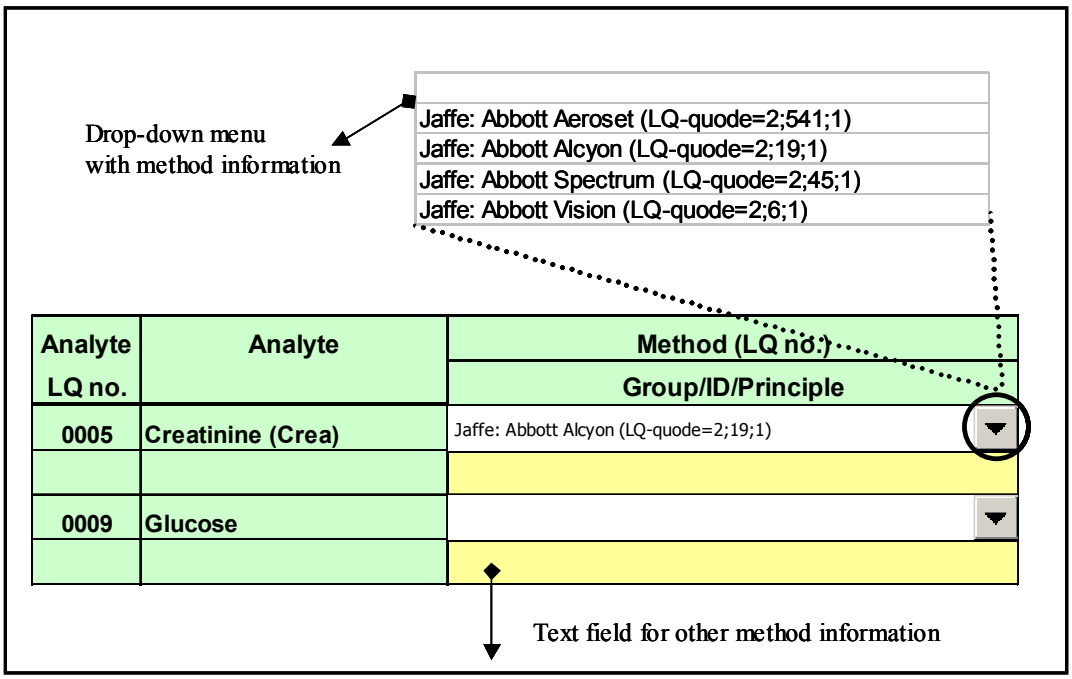


Figure 3. Section from sheet 2 of the report form.

4.3. Sample distribution and deadline for reporting results

During spring 2002, approximately 1 200 sets of samples were shipped from IRMM to the regional coordinators. The parcels with the samples contained dry ice sufficient for at least 48 hours. Where possible, a courier was used to facilitate transport and customs clearance. For the longest distances, and in those cases where the whole transport chain could not be sufficiently planned in advance, the parcel was equipped with a recorder to monitor time and temperature conditions.

The coordinators arranged the surveys and forwarded the samples to the participants as appropriate. The deadline for reporting results was initially set to 31 May but was postponed for three weeks due to logistic problems.

5. Results and discussion

5.1. Participation in IMEP-17

5.1.1. Country of origin

Report forms from 1 037 participants had been collected when the deadline expired. The participants came from 35 countries on all continents (Table 6).

Table 6. Number of participants per country.

Country	Number of participants	Country	Number of participants
Albania	5	Italy	56
Argentina	23	Mexico	33
Australia	39	New Zealand	17
Austria	49	Norway	51
Belgium	49	Poland	64
Bulgaria	23	Portugal	38
Canada	29	Romania	8
China	27	Slovakia	41
Croatia	28	Slovenia	5
Cyprus	14	South Africa	6
Czech Republic	30	Spain	26
Denmark	53	Sweden	83
Estonia	5	The Netherlands	27
Finland	12	Turkey	14
Germany	20	United kingdom	31
Hungary	4	USA	53
Iceland	1	Yugoslavia	37
Israel	36		
		Total:	**1 037**

5.1.2. Laboratory description

The coordinators were free to select the participants. Figure 4 gives a rough indication about the type and relative distribution of the laboratories.

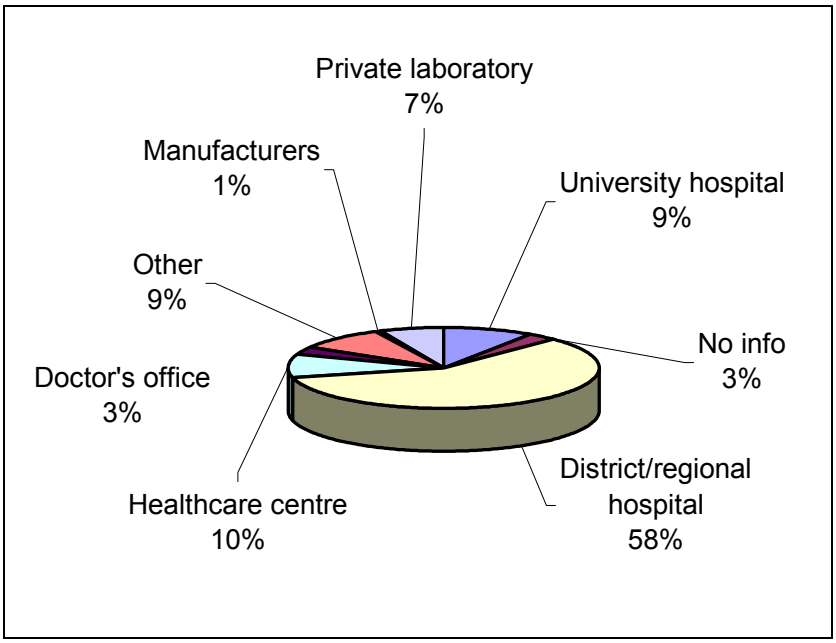


Figure 4. Type and relative distribution of laboratories participating in IMEP-17.

5.1.3. Quality management system

The majority (75%) of the participants replied positively when they were asked to indicate if their laboratory has a quality management system implemented (below). The no-fraction was represented by 28 of the 35 countries.

Option:	Yes	No	No information
%:	74,7	21,6	3,7

5.1.4. Survey organisation

The coordinators organised their respective survey differently. Some examples: in, e.g. Sweden, the IMEP-17 samples replaced lyophilised materials in two consecutive monthly rounds of a general clinical chemistry scheme. In four other Nordic countries, the two samples were measured on one occasion but in parallel with three other serum calibrators and control materials. One objective was to transfer the accuracy of the IMEP-17 samples to the other materials [35]. In Italy, where no national EQA scheme exists, the coordinators managed to obtained participants from regional schemes all over the country. The Slovak coordinator organised a meeting in connection with a national workshop. Here, the candidate participants received information about the survey and could discuss the translated documentation. In addition, special training in uncertainty evaluation was provided. Other countries arranged laboratories to come and collect the frozen samples from the coordinator.

5.2. Collection and processing of results

5.2.1. Data extraction and confirmation

The regional coordinators collected and forwarded the report forms to IRMM. Each report form was checked for inconsistencies, e.g. changes in structure and/or vital missing information (e.g. units) that would interfere with the processing and evaluation. Where necessary, the regional coordinators or the participants were asked to supply additional information.

The information in report forms was then extracted and compiled into four sheets in a single Microsoft® Excel file. In the extraction, a macro written in Microsoft® Visual Basic [36] was used. The information was then imported into a Microsoft® Access database from which the graphical display was prepared. At this stage, additional checks had resulted in a list with about 300 suspicious results for Material 1 and some 150 for Material 2. Most of these were clearly caused by participants selecting the wrong unit in the drop-down menus. With the consent of the regional coordinators, the correct unit was inserted.* Note that the numerical values remained as originally reported.

5.2.2. Comments on units and measurands

Although the measurands were clearly specified in the instructions, some report forms contained results for other measurands. Such results were removed if the information from the participants in the report form, or the coordinator confirmed this. Still there might be some results for, e.g. free thyroxine and pancreas amylase that have slipped through.

5.2.2.1 Reported units

The participants reported results in their units of choice. The report form contained a drop-down menu from which nine common units could be selected. In this report, the certified values and participants' results are presented in mmol/L, μmol/L, nmol/L, g/L, or U/L (e.g. Table 3 and Annex 1). The participants also used μg/dL, μkat/L, g/dL and mg/dL (Table 7). In addition, a few results for electrolytes were expressed in equivalents/L.

5.2.2.2 Use of katal

The name 'katal' is well established in IFCC and IUPAC, and it has been used since the 1960:s to express catalytic activity. In 1999, this name became an official part of the SI system [37]. For this reason, and because a known conversion factor exists, kat/L is preferred to the non-SI unit U/L. Most participants in IMEP-17 reported their results for amylase and γ-GT in U/L (Table 7). Participants from Slovenia, Czech Republic, Slovak Republic and Sweden used consistently μkat/L.

5.2.2.3 Urea nitrogen

It is common in the United States to report and express results of urea assays as Urea-N [38]. It is suspected that all but two US participants did so, although, only a few of them actually stated this in their report form. It is likely that also some thirty participants from China, Germany, Italy, Poland, Turkey, Mexico and Austria also reported results as Urea-N. The lower part of Figure 17 in Annex 1 reflects this.

* This type of mistakes is mainly caused by the added difficulty that the report form itself constitute. If included, the graphical display would not illustrate correctly the participants' measurement capability.

5.2.2.4 Comparability of enzyme measurements

Results of catalytic concentrations of enzymes are only comparable when the enzyme activities are measured under the very same conditions. Figure 12 in Annex 1 illustrates the complexity of situation and indicates various calibration levels. E.g., most of the Norwegian, Danish and Finnish participants' results are calibrated to the so-called Phadebas® level and appears at around 190 U/L. The work with adjusting routine methods to the levels given by the IFCC reference measurement procedures is on-going.

5.2.2.5 Measurements of creatinine

Most chemical methods for measurement of creatinine in serum are so-called Jaffe methods, i.e. they are primarily based on the reaction with alkaline picrate. This reaction is not specific for creatinine and various approaches have been made to overcome or correct for interferences. A detailed description is needed in order to decide which creatinine results can be compared.

Table 7. Number of results per component grouped according to the units in which they were reported by the participants. Data for components in Material 1 and for Li in Material 2.

Component	Units used by the participants									
	U/L	µkat/L	mmol/L	µmol/L	nmol/L	g/dL	g/L	mg/dL	µg/dL	**Σ**
Albumin				26		317	557	18		918
Amylase	764	99								863
Ca			671					312		983
Cholesterol			552			1	11	427		991
Cl			790							790
Creatinine			30	547				445		1022
Cu				82				2	54	138
Fe				479				1	389	869
Glucose			565				21	425		1011
γ-GT	809	141								950
IgG				9		1	283	219		512
K			999							999
Mg			551					286		837
Li			449							449
Na			992							992
Se				10	1				10	21
Thyroxine (T4)			1	1	91				126	219
Urea			557				19	428		1004
Uric acid			156	396			1	440		993
Zn				86				2	47	135

5.2.3. Participants' uncertainty statements

The participants could specify in the report form if and how the uncertainty was reported. As expected, the majority (62%) would, if requested, provide a precision statement derived from their control chart (Table 8). Of the 490 participants that actually provided an uncertainty statement with their results, 88% reported it as a total variation between days. Where appropriate, the graphical display in Annex 1 includes the uncertainties.

Table 8. Overview of the uncertainty information provided by the participants. The numbers in column A refer to the question "how the laboratory reports the uncertainty?". The numbers in column B shows the distribution of the different statements from the 490 participants that actually provided uncertainty statements for their measurements on Material 1.

Uncertainty statement	A	B
	Fraction (%) of all 1 037 participants	**Fraction (%) of the 490 participants that reported an uncertainty**
Total variation between days (CV%)	62	88
Total analytical error (TE %)	4	5
Expanded uncertainty with coverage factor (U, k=2)	1	2
Other	4	4
Don't know	17	1
No information	12	1

6. Graphical display of results

6.1. Explanatory remarks

6.1.1. The IMEP graph

In Figure 5 we show an example of how results are displayed in IMEP. For each set of data, the participants' results are plotted in ascending order against the certified value. The scale of the graph, around the certified value, is chosen for convenience. No results are excluded but those that are off-scale are presented in textboxes on the graphs.

One objective of IMEP is to show how results obtained under routine conditions agree on an international level. Unless otherwise stated, each participant's data is therefore the result of a single measurement. The participants' self-declared uncertainty statements are included in some graphs but the reader should be aware that they are expressed differently (Section 5.2.3) and may cover different steps of the measurement procedure. Additional data, a maximum of nine other replicates over five days, will be discussed in Part 2 of this report.

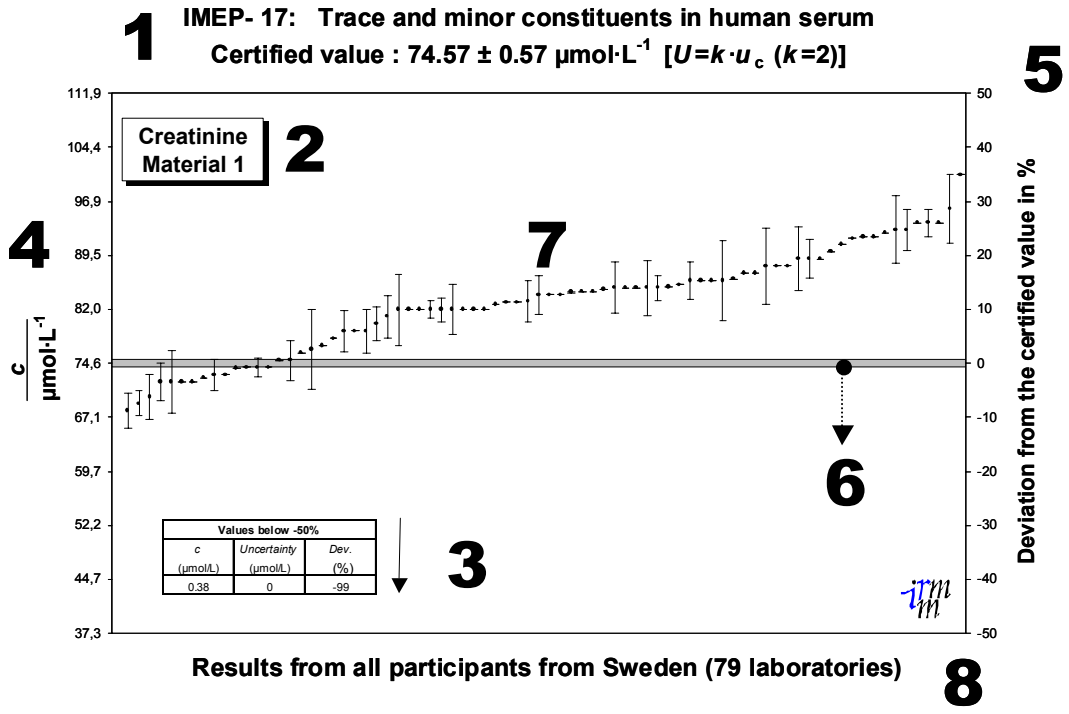


Figure 5. Description of the content displayed in the result graphs:

1. Legend with project name and certified value for the displayed component.
2. Component name and material.
3. Box indicating results falling outside the scale of the graph.
4. Scale with the value of the quantity expressed in absolute numbers.
5. Scale with the value of the quantity expressed in % relative deviation from the certified value.
6. Range (shaded) encompassing the certified value and its expanded uncertainty.
7. Participant's result (single measurement unless otherwise stated) and self-declared uncertainty.
8. Legend explaining details of the graph.

6.1.2. Method grouping – Pros and cons

In principle, it would be possible to describe each participants' measurement in great detail, e.g. in the following way:

> *Laboratory XXX analyses S-Amylase using a Roche EPS 1555693 kit and Roche calibrator for automated systems 759350. The instrument is a Hitachi 911 and the reference value is <100 U/L*

Such information must be included in the laboratory's description of its measurement procedure, and is much used when EQA scheme organisers evaluate laboratory and method performance. A glance in Reference 9 reveals that there are close to 80 different measuring systems for amylase, and typically between 5 and 50 for the other components in IMEP-17. Also when measuring systems are grouped together, the situation can be complex as illustrated by the fourteen method groups for S-amylase in Reference 9.

Even with so detailed information as described above, it is not obvious that a result is comparable with that obtained by another measuring system. This may lead to complications, e.g. when a patient is transferred from one hospital to another. The situation can be improved through use of an international coding system. The IFCC-IUPAC coding system for nomenclature, properties and units (NPU) gives a clear description of what intends to be measured [39] but has been implemented in only a few countries. The concept of traceability (Section 3.2.3) also offers a simple basis for comparability. Manufacturers should clearly state to which reference point (Figure 2) results with their measuring systems are traceable. The IVD directive with its requirements [6], and new international standards, e.g. [25] are important steps in this direction.

The graphical display contains the major method groups as defined in Reference 9. Where there only exist a few results for a method group, or where participants have referred to other measuring systems on the market, their results are grouped in "Other/no info". It is not within the scope of IMEP-17 to compare existing methods in detail but additional information can be obtained on request.

6.2. Report to participants - Part 1

Annex 1 of this report provides an overview of results as reported by all participants for the nineteen components in Material 1 and Li in Material 2. The main objective is to illustrate how well routine measurement results all over the world agree with values traceable to higher metrological order (see point 6 in Figure 5). Additional graphs illustrate results in selected countries/regions, and according to defined method groups.

6.3. Report to participants - Part 2

Part 2 of this report will focus on the results for the remaining components in Material 2, evaluate the results for replicate measurements, illustrate laboratory performance with Youden diagrams, and discuss quality specifications.

6.4. Supplementary information

The large amount of information prevents a complete graphical display to be printed here. IRMM will provide regional coordinators and other interested parties with a set of national graphs [40]. A database with all raw data (in laboratory coded form) will be made available to those interested. It will enable further analysis of the results.

Acknowledgements

The authors thank the members of the C-AQ IFCC and EQALM for their continuous support and guidance throughout the project. The work of scientists involved in the establishment of reference measurement procedure values, and the coordination of participants is gratefully acknowledged. Valuable support and advice has been received from people within the CCQM, IUPAC, Eurachem, Euromet, Eurolab and CITAC. Dr S. Linko and Mr R. Kessel took part in the development of the special educational aspect of the project. We are also indebted to Mrs M. De Smet, Dr Yetunde Aregbe, previous members of the IMEP group, and all other colleagues at IRMM who offered administrative and logistic assistance throughout this project. Finally we would like to thank explicitly professor Paul De Bièvre for the useful advice and guidance that he offered for the accomplishment of the IMEP aims.

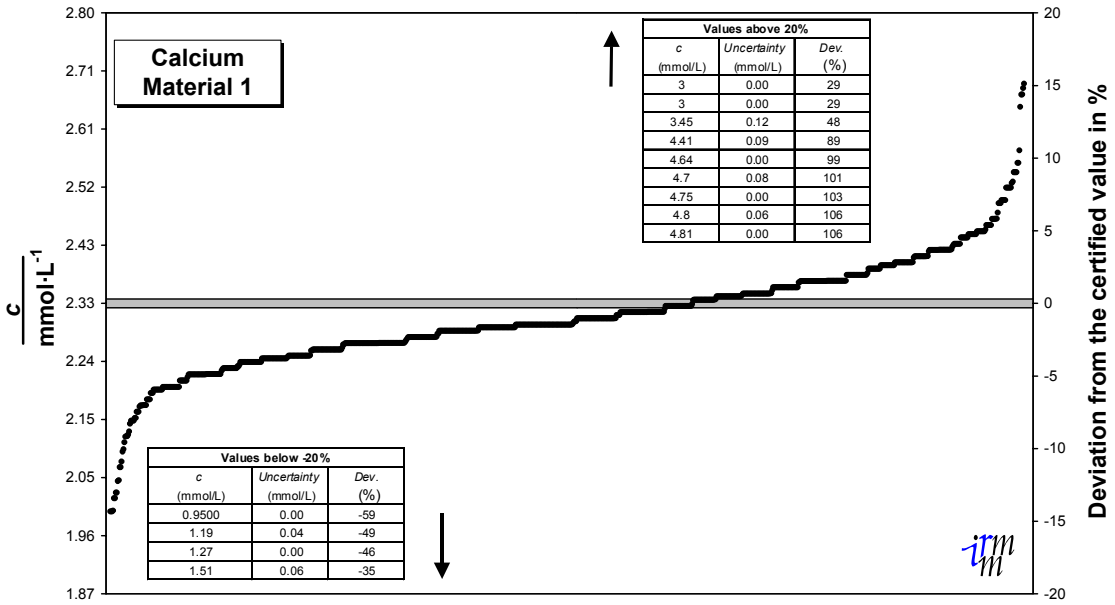
Annex 1 - Graphical presentation

Figure nr.	Component	Material	Description
			General graphs
1	Ca	1	Single results from all reporting laboratories
2	Cl	1	
3	Cu	1	
4	Fe	1	
5	Mg	1	
6	K	1	
7	Se	1	
8	Na	1	
9	Li	2	
10	Zn	1	
11	Albumin	1	
12	Amylase	1	
13	Cholesterol	1	
14	Creatinine	1	
15	γ-GT	1	
16	Glucose	1	
17	Urea	1	
18	IgG	1	
19	Thyroxine (T4)	1	
20	Uric acid	1	
			Method graphs
21	Creatinine	1	Single results from all reporting laboratories arranged in method groups
22	Amylase	1	
23	Urea	1	
24	Glucose	1	
25	γ-GT	1	
26	Cholesterol	1	
			National/regional graphs
			Single results from all reporting laboratories in region:
27	Amylase	1	Africa
28	Amylase	1	Asia-Pacific
29	Amylase	1	EU candidate countries
30	Amylase	1	EU countries
31	Amylase	1	Nordic countries
32	Amylase	1	North America
33	Amylase	1	South + Central America
34	Amylase	1	Albania, Croatia, Israel, Yugoslavia
35	γ-GT	1	Nordic countries
36	γ-GT	1	North America
37	γ-GT	1	Asia-Pacific
38	Creatinine	1	EU candidate countries
39	Creatinine	1	Results from region EU countries
40	Creatinine	1	Results from region South + Central America

IMEP-17
Participants' results.
General graphs by component

Fig. 1

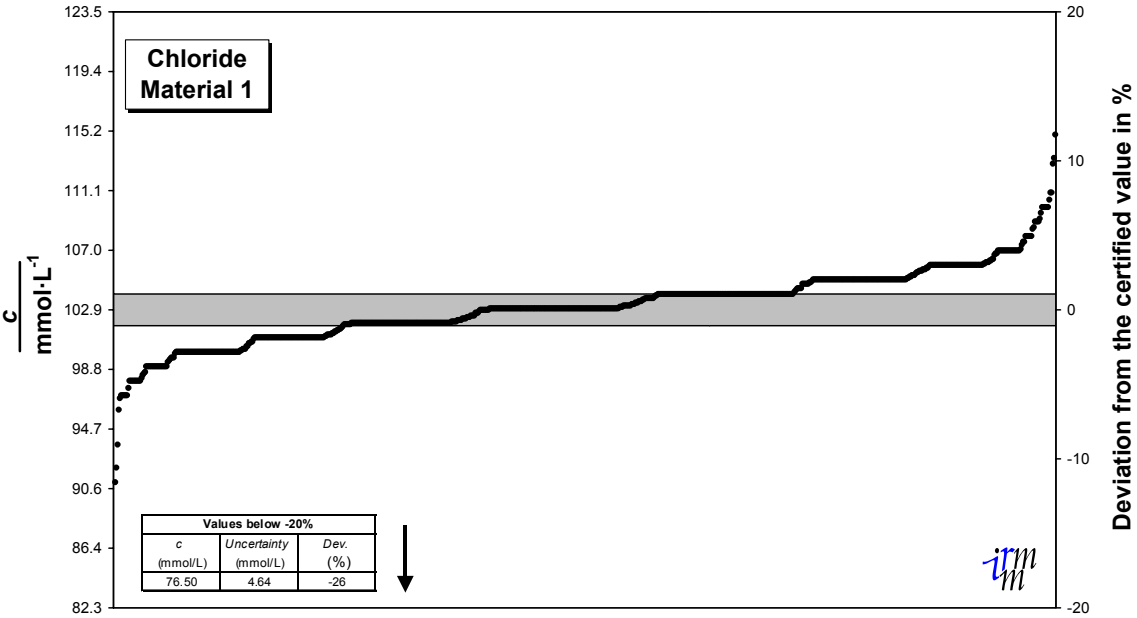
IMEP- 17: Trace and minor constituents in human serum
Certified value : 2.334 2 ± 0.006 9 mmol·L^{-1} [$U = k \cdot u_c$ (k=2)]



Results from all participants (983 laboratories)

Fig. 2

IMEP- 17: Trace and minor constituents in human serum
Certified value : 102.9 ± 1.1 mmol·L^{-1} [$U = k \cdot u_c$ (k=2)]



Results from all participants (790 laboratories)

Fig. 3

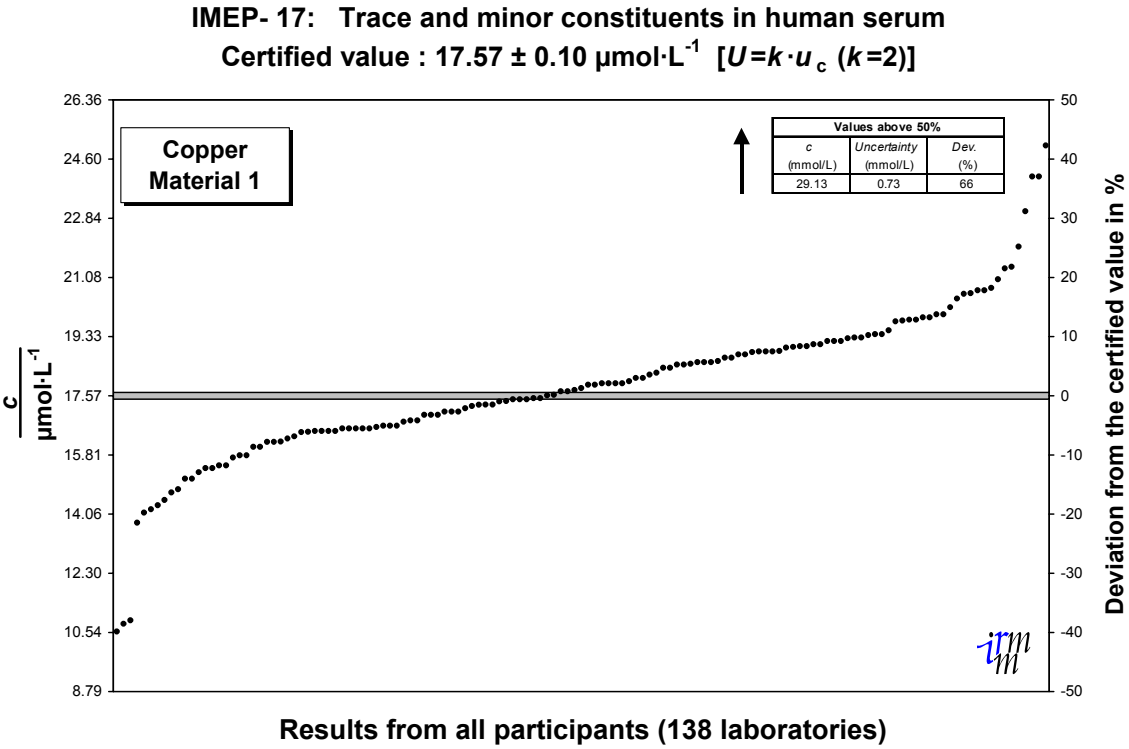

IMEP- 17: Trace and minor constituents in human serum
Certified value : 17.57 ± 0.10 µmol·L-1 [U=k·uc (k=2)]
Copper
Material 1
Values above 50%
c (mmol/L) | Uncertainty (mmol/L) | Dev. (%)
29.13 | 0.73 | 66
c / µmol·L-1
Deviation from the certified value in %
26.36
24.60
22.84
21.08
19.33
17.57
15.81
14.06
12.30
10.54
8.79
50
40
30
20
10
0
-10
-20
-30
-40
-50
Results from all participants (138 laboratories)

Fig. 4

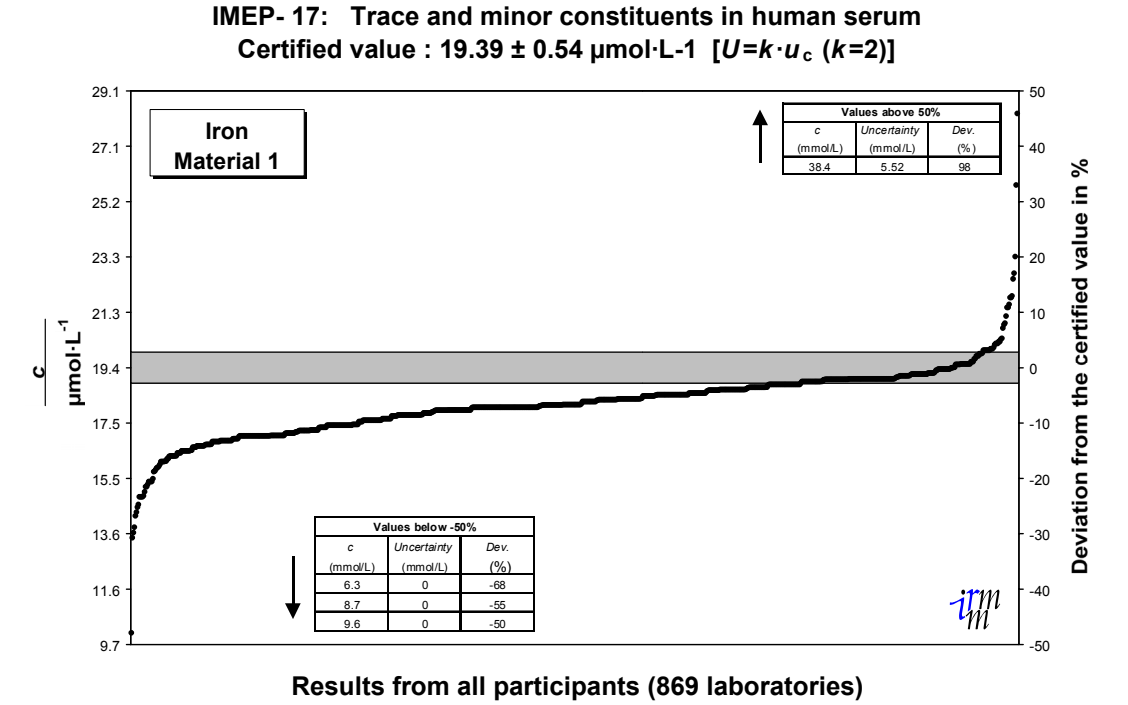

IMEP- 17: Trace and minor constituents in human serum
Certified value : 19.39 ± 0.54 µmol·L-1 [U=k·uc (k=2)]
Iron
Material 1
Values above 50%
c (mmol/L) | Uncertainty (mmol/L) | Dev. (%)
38.4 | 5.52 | 98
Values below -50%
c (mmol/L) | Uncertainty (mmol/L) | Dev. (%)
6.3 | 0 | -68
8.7 | 0 | -55
9.6 | 0 | -50
c / µmol·L-1
Deviation from the certified value in %
29.1
27.1
25.2
23.3
21.3
19.4
17.5
15.5
13.6
11.6
9.7
50
40
30
20
10
0
-10
-20
-30
-40
-50
Results from all participants (869 laboratories)

Fig. 5

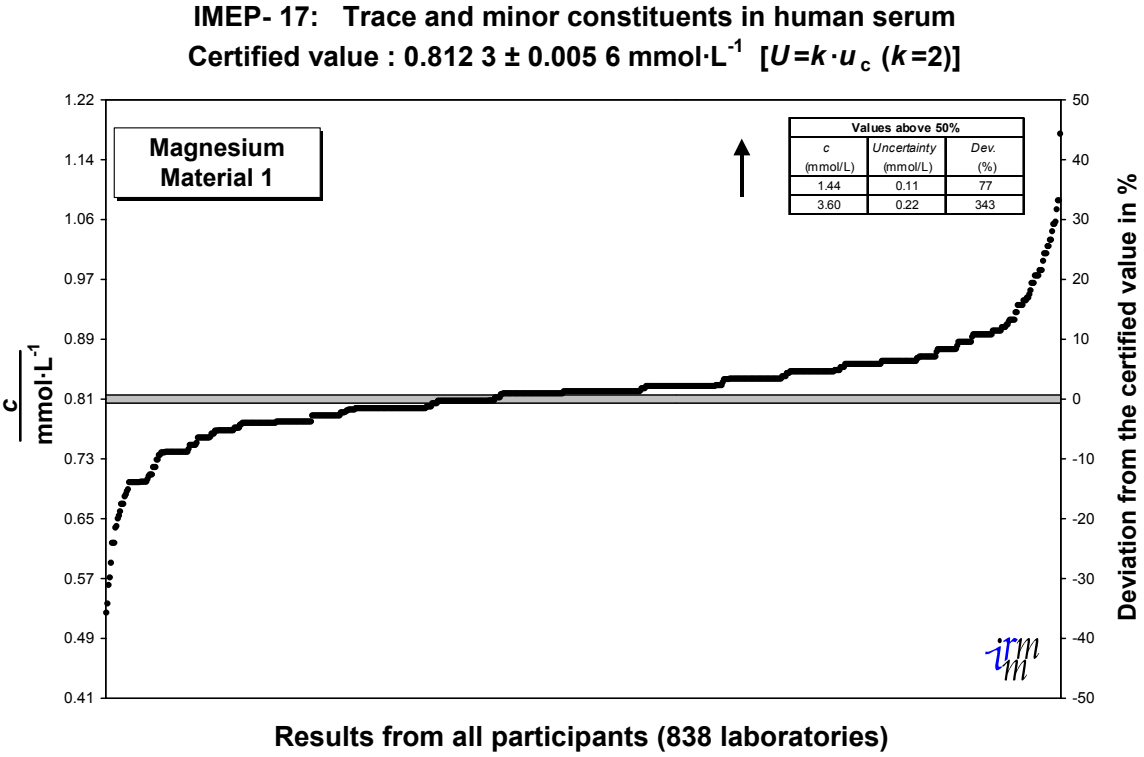

IMEP- 17: Trace and minor constituents in human serum
Certified value : 0.812 3 ± 0.005 6 mmol·L-1 [U=k·uc (k=2)]
Magnesium
Material 1
Values above 50%
c (mmol/L) | Uncertainty (mmol/L) | Dev. (%)
1.44 | 0.11 | 77
3.60 | 0.22 | 343
c / mmol·L-1
Deviation from the certified value in %
Results from all participants (838 laboratories)

Fig. 6

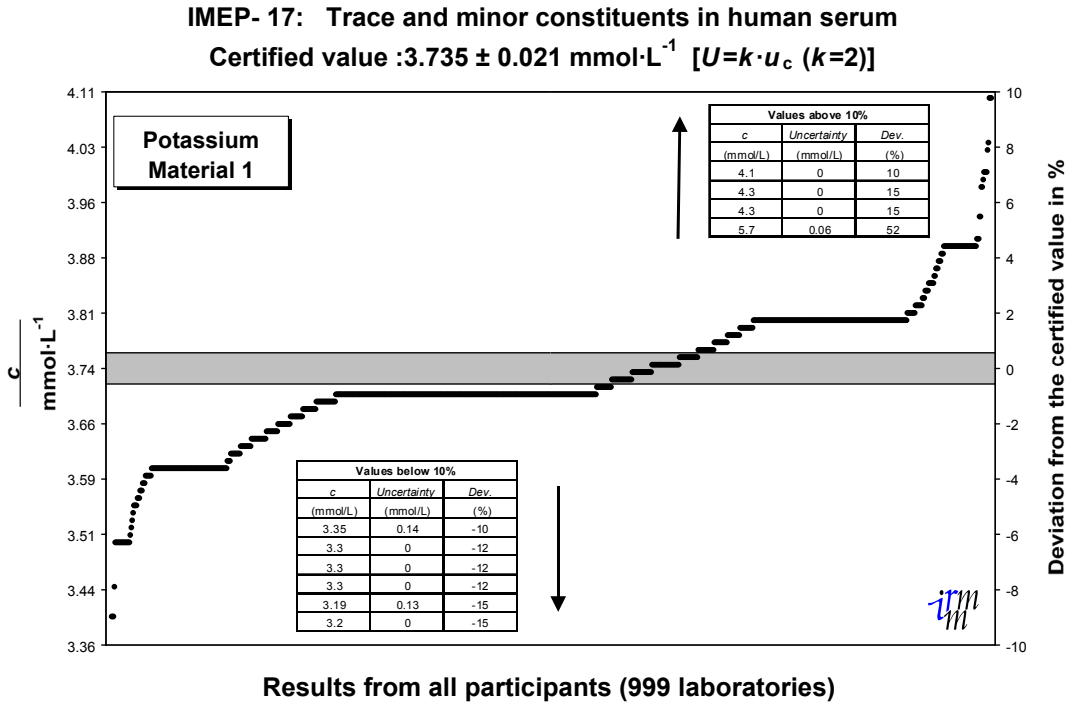

IMEP- 17: Trace and minor constituents in human serum
Certified value :3.735 ± 0.021 mmol·L-1 [U=k·uc (k=2)]
Potassium
Material 1
Values above 10%
c (mmol/L) | Uncertainty (mmol/L) | Dev. (%)
4.1 | 0 | 10
4.3 | 0 | 15
4.3 | 0 | 15
5.7 | 0.06 | 52
Values below 10%
c (mmol/L) | Uncertainty (mmol/L) | Dev. (%)
3.35 | 0.14 | -10
3.3 | 0 | -12
3.3 | 0 | -12
3.3 | 0 | -12
3.19 | 0.13 | -15
3.2 | 0 | -15
c / mmol·L-1
Deviation from the certified value in %
Results from all participants (999 laboratories)

Fig. 7

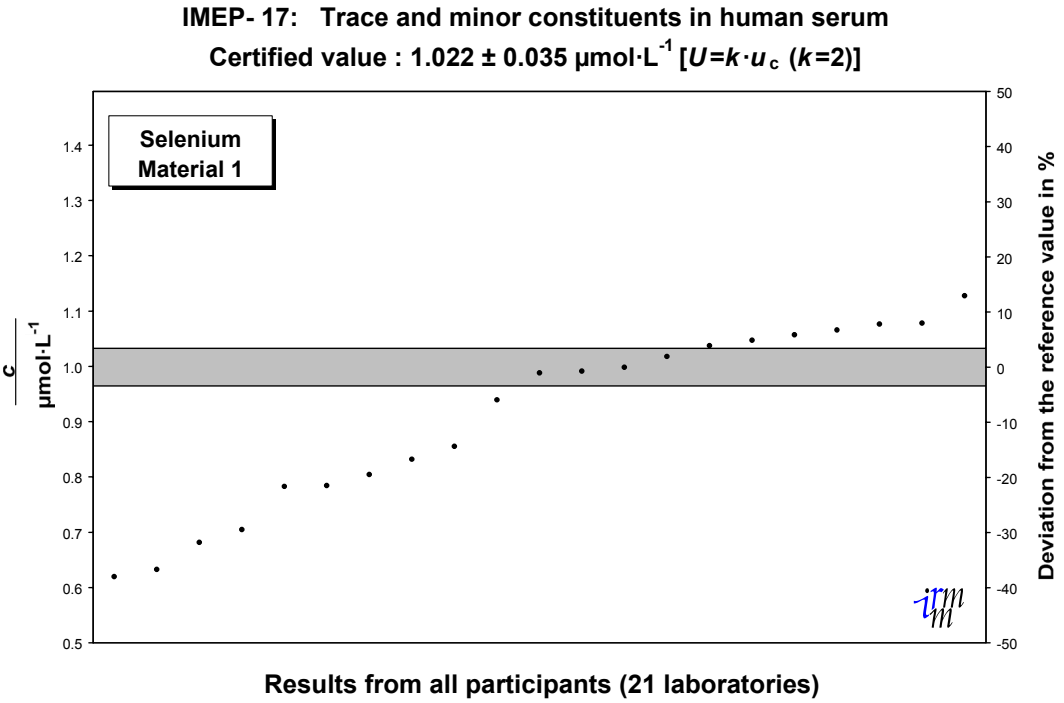

IMEP- 17: Trace and minor constituents in human serum
Certified value : 1.022 ± 0.035 µmol·L-1 [U=k·uc (k=2)]
Selenium
Material 1
c
µmol·L-1
Deviation from the reference value in %
Results from all participants (21 laboratories)

Fig. 8

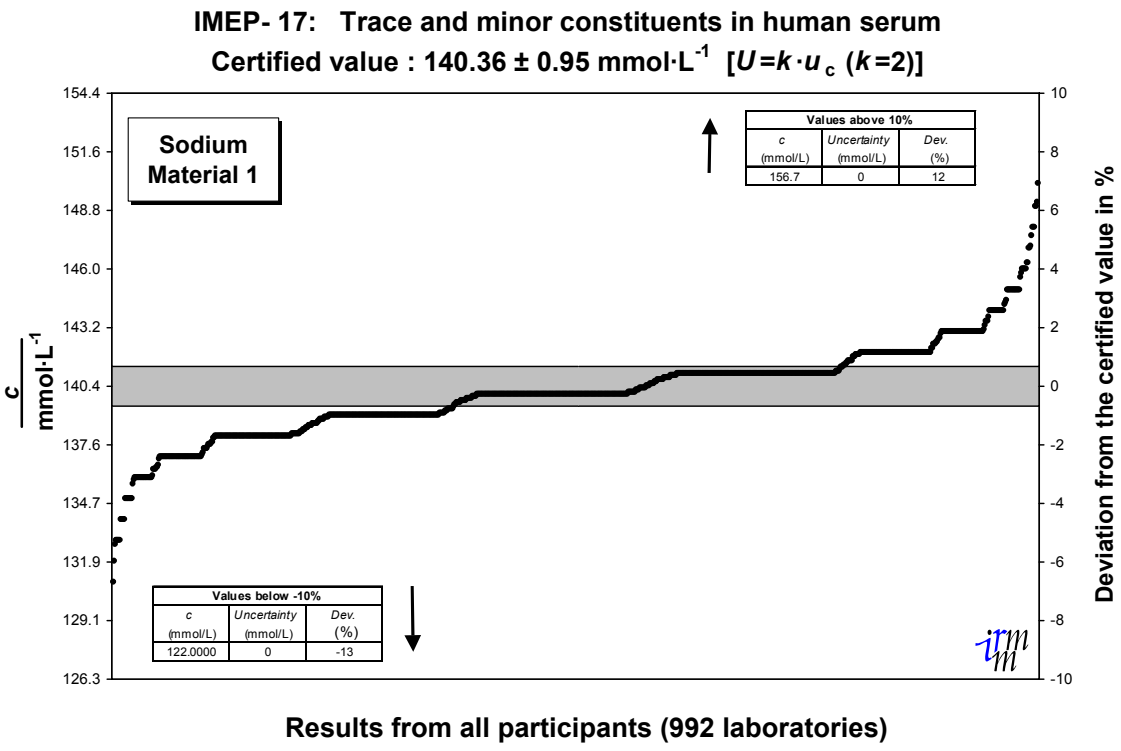

IMEP- 17: Trace and minor constituents in human serum
Certified value : 140.36 ± 0.95 mmol·L-1 [U=k·uc (k=2)]
Sodium
Material 1
Values above 10%
c (mmol/L) | Uncertainty (mmol/L) | Dev. (%)
156.7 | 0 | 12
Values below -10%
c (mmol/L) | Uncertainty (mmol/L) | Dev. (%)
122.0000 | 0 | -13
c
mmol·L-1
Deviation from the certified value in %
Results from all participants (992 laboratories)

Fig. 9

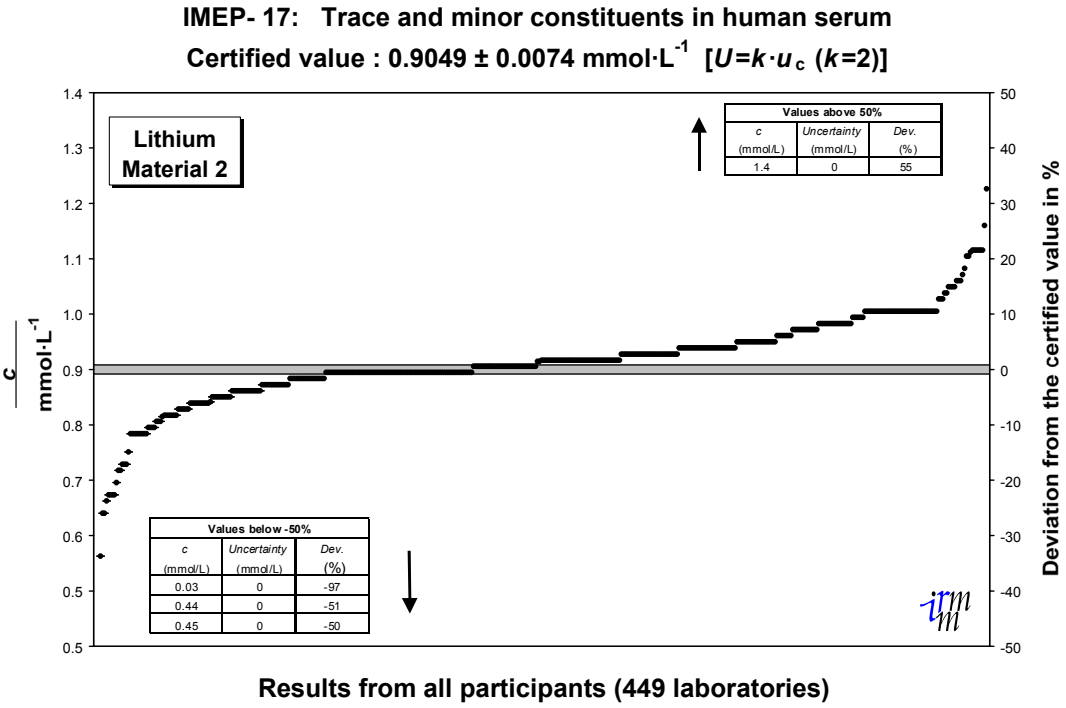

IMEP- 17: Trace and minor constituents in human serum
Certified value : 0.9049 ± 0.0074 mmol·L-1 [U=k·uc (k=2)]
Lithium
Material 2
Values above 50%
c (mmol/L) | Uncertainty (mmol/L) | Dev. (%)
1.4 | 0 | 55
Values below -50%
c (mmol/L) | Uncertainty (mmol/L) | Dev. (%)
0.03 | 0 | -97
0.44 | 0 | -51
0.45 | 0 | -50
c mmol·L-1
Deviation from the certified value in %
Results from all participants (449 laboratories)

Fig. 10

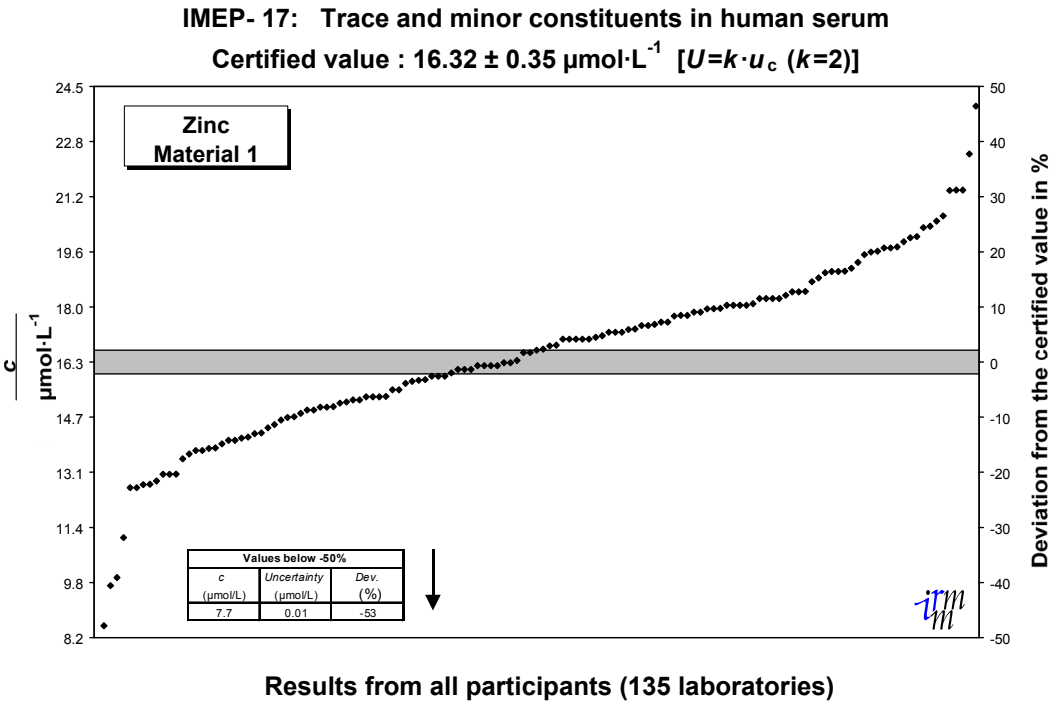
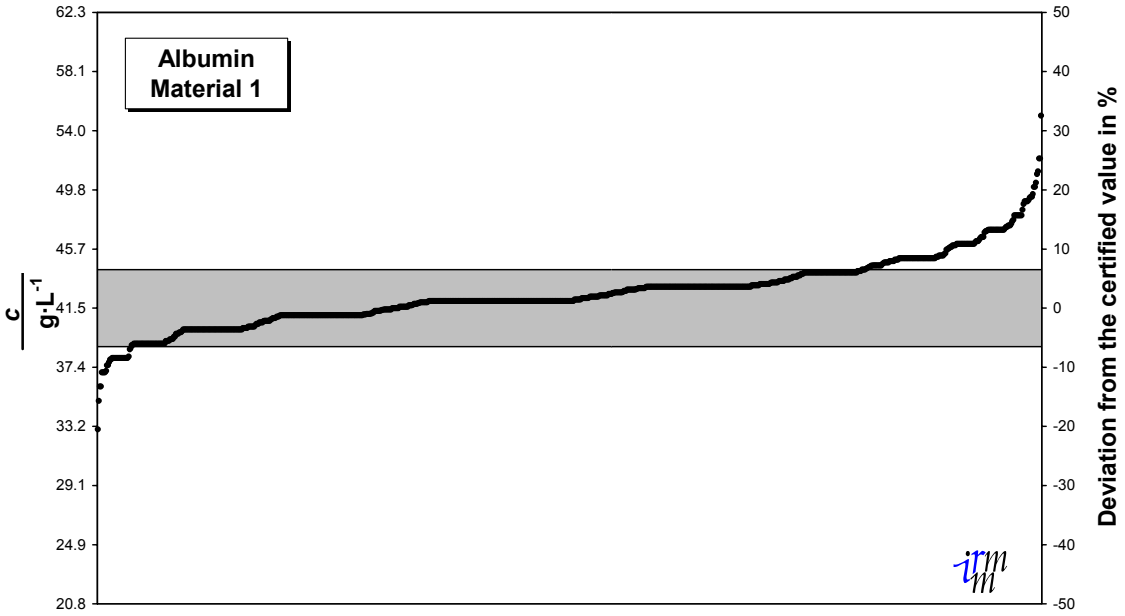

IMEP- 17: Trace and minor constituents in human serum
Certified value : 16.32 ± 0.35 µmol·L-1 [U=k·uc (k=2)]
Zinc
Material 1
Values below -50%
c (µmol/L) | Uncertainty (µmol/L) | Dev. (%)
7.7 | 0.01 | -53
c µmol·L-1
Deviation from the certified value in %
Results from all participants (135 laboratories)

Fig. 11

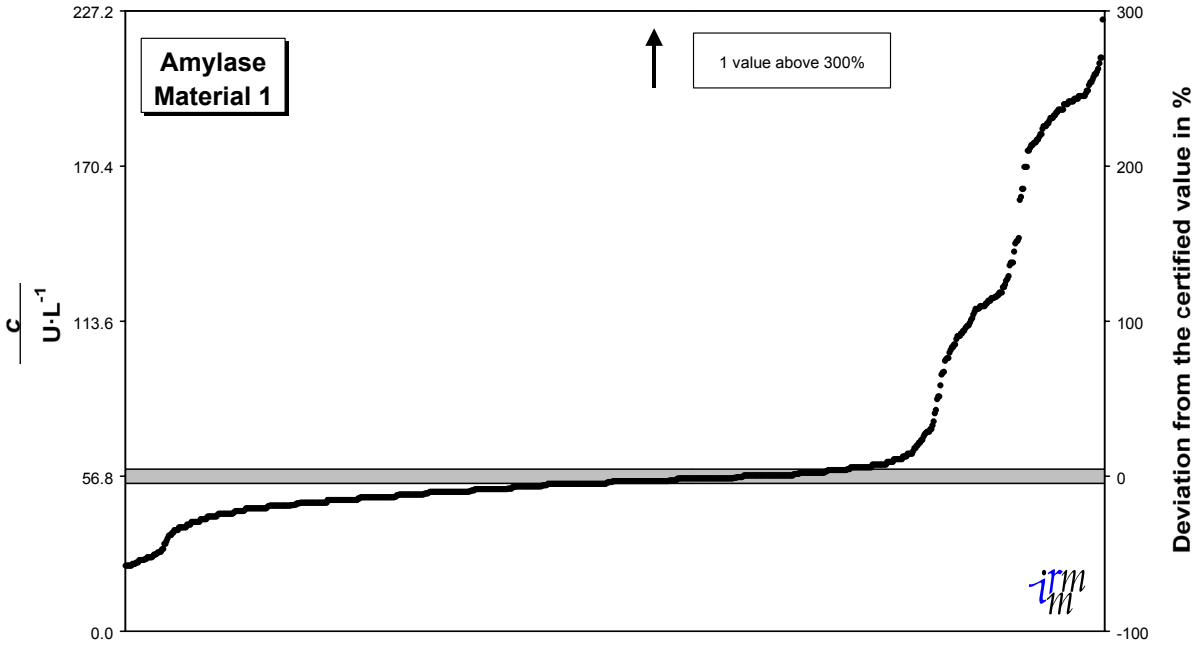
IMEP- 17: Trace and minor constituents in human serum
Certified value : 41.5 ± 2.7 g·L^{-1} [$U = k \cdot u_c$ (k=2)]



Results from all participants (918 laboratories)

Fig. 12

IMEP- 17: Trace and minor constituents in human serum
Certified value : 56.8 ± 2.6 U·L^{-1} [$U = k \cdot u_c$ (k=2)]



Results from all participants (863 laboratories)

Fig. 13

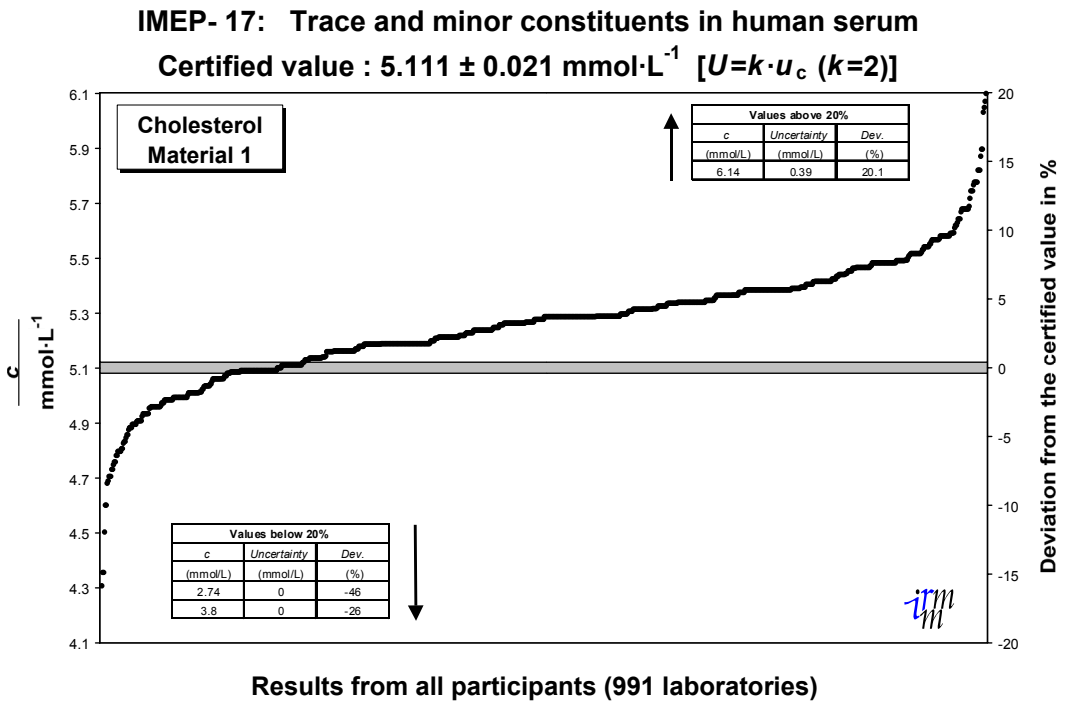

IMEP- 17: Trace and minor constituents in human serum
Certified value : 5.111 ± 0.021 mmol·L-1 [U=k·uc (k=2)]
Cholesterol Material 1
Values above 20%
c (mmol/L) | Uncertainty (mmol/L) | Dev. (%)
6.14 | 0.39 | 20.1
Values below 20%
c (mmol/L) | Uncertainty (mmol/L) | Dev. (%)
2.74 | 0 | -46
3.8 | 0 | -26
c mmol·L-1
Deviation from the certified value in %
Results from all participants (991 laboratories)

Fig. 14

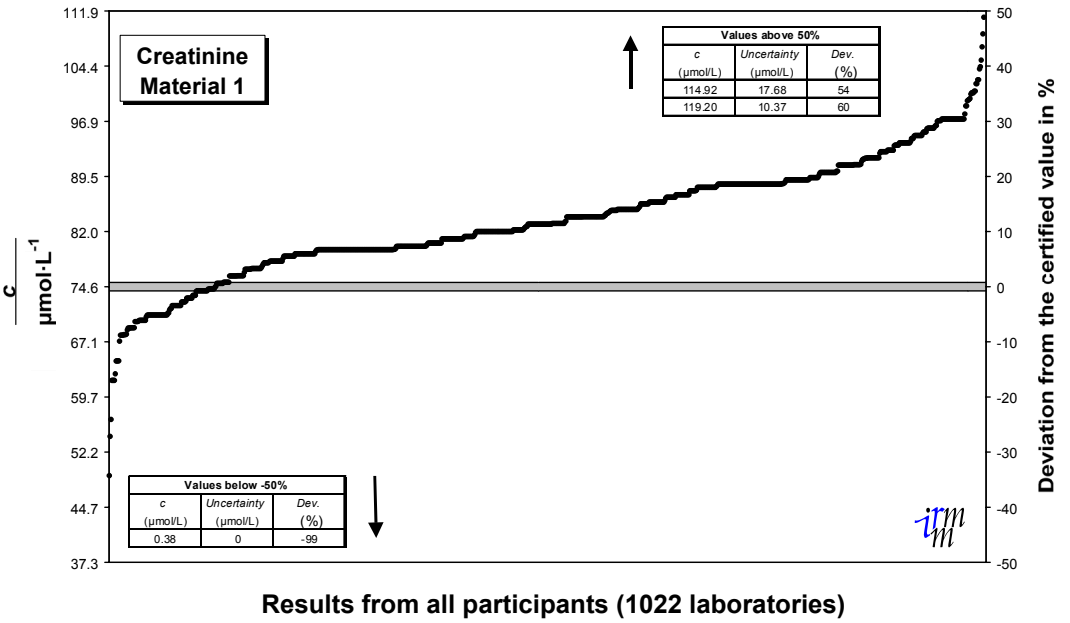
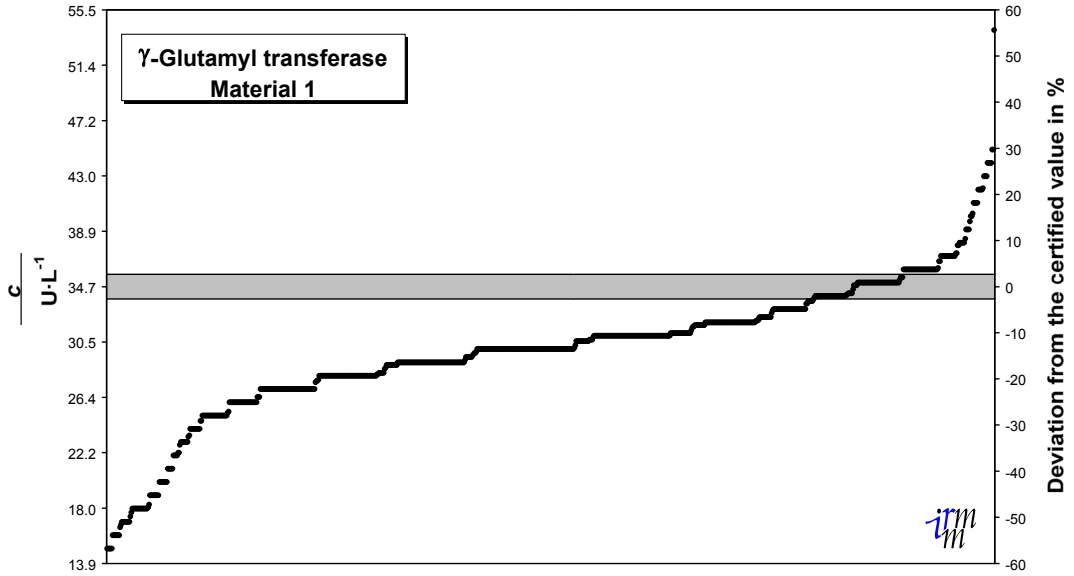

IMEP- 17: Trace and minor constituents in human serum
Certified value : 74.57 ± 0.57 µmol·L-1 [U=k·uc (k=2)]
Creatinine Material 1
Values above 50%
c (µmol/L) | Uncertainty (µmol/L) | Dev. (%)
114.92 | 17.68 | 54
119.20 | 10.37 | 60
Values below -50%
c (µmol/L) | Uncertainty (µmol/L) | Dev. (%)
0.38 | 0 | -99
c µmol·L-1
Deviation from the certified value in %
Results from all participants (1022 laboratories)

Fig. 15

IMEP- 17: Trace and minor constituents in human serum

Certified value : 34.70 ± 0.93 U·L^{-1} [$U=k\cdot u_c$ (k=2)]

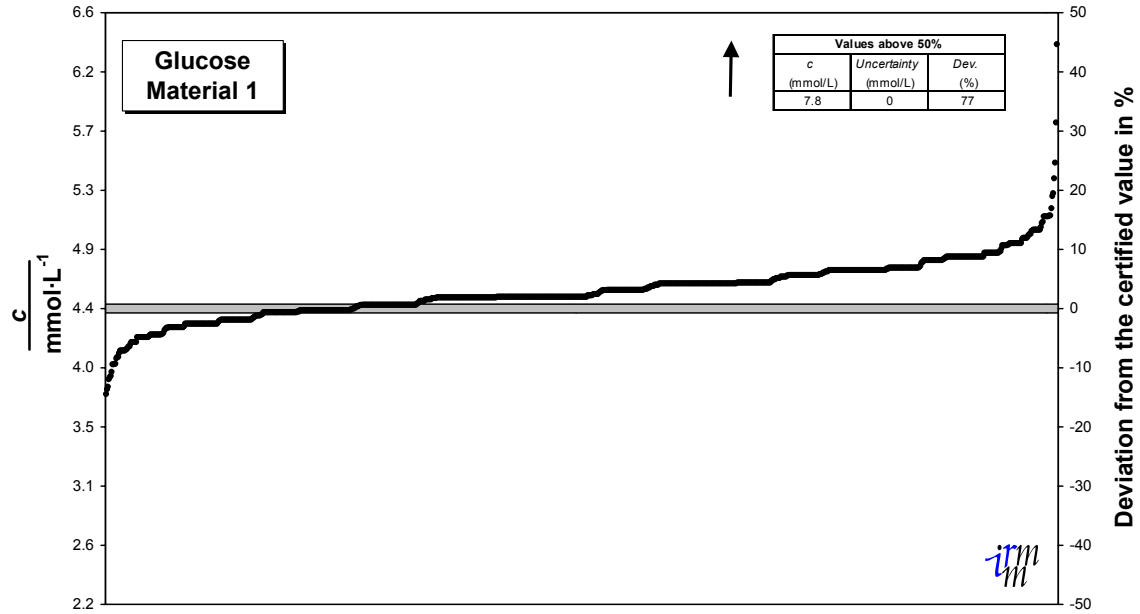


Results from all participants (950 laboratories)

Fig. 16

IMEP- 17: Trace and minor constituents in human serum

Certified value : 4.412 ± 0.033 mmol·L^{-1} [$U=k\cdot u_c$ (k=2)]



Results from all participants (1011 laboratories)

Fig. 17

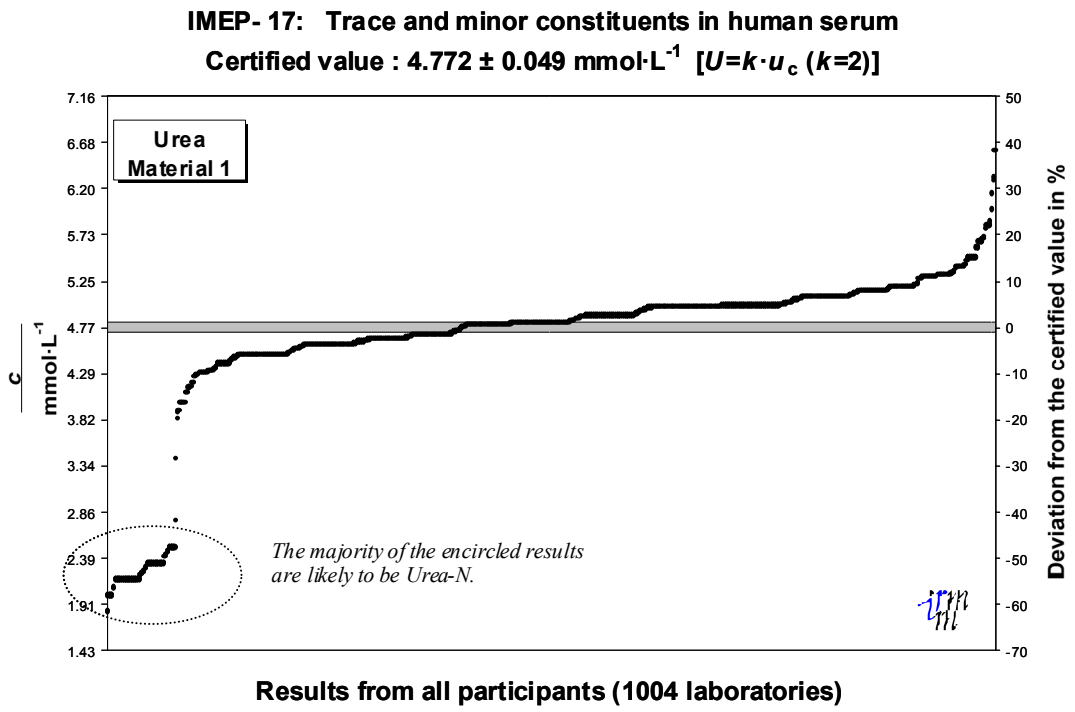

IMEP- 17: Trace and minor constituents in human serum
Certified value : 4.772 ± 0.049 mmol·L-1 [U=k·uc (k=2)]
Urea
Material 1
The majority of the encircled results
are likely to be Urea-N.
c
mmol·L-1
Deviation from the certified value in %
Results from all participants (1004 laboratories)

Fig. 18

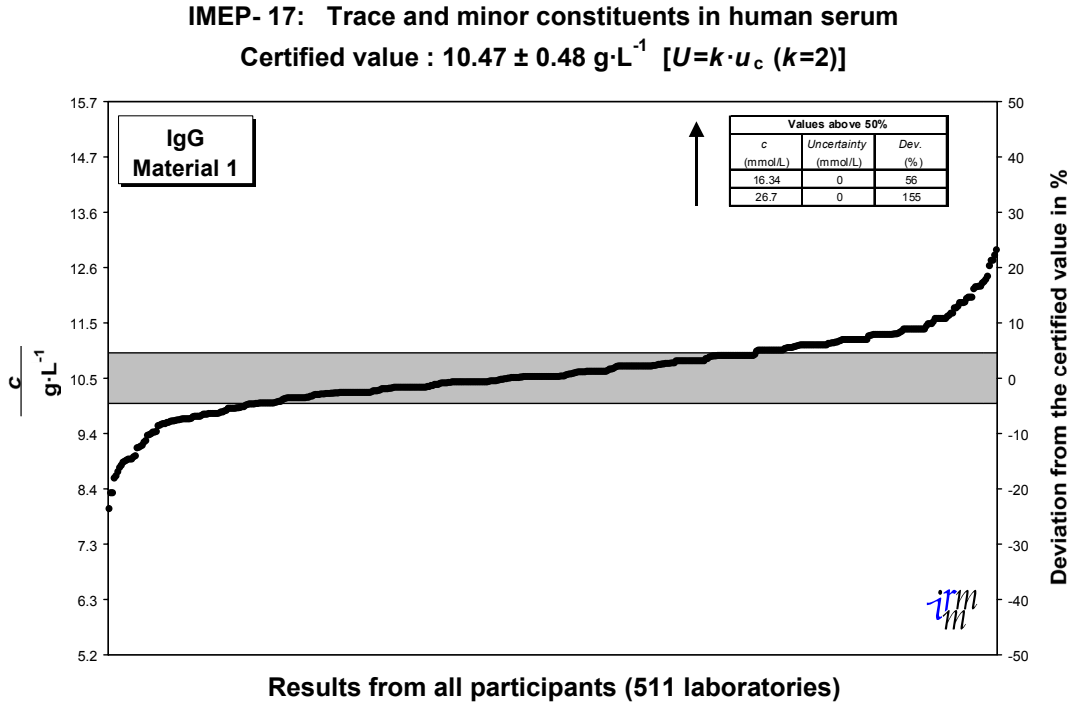
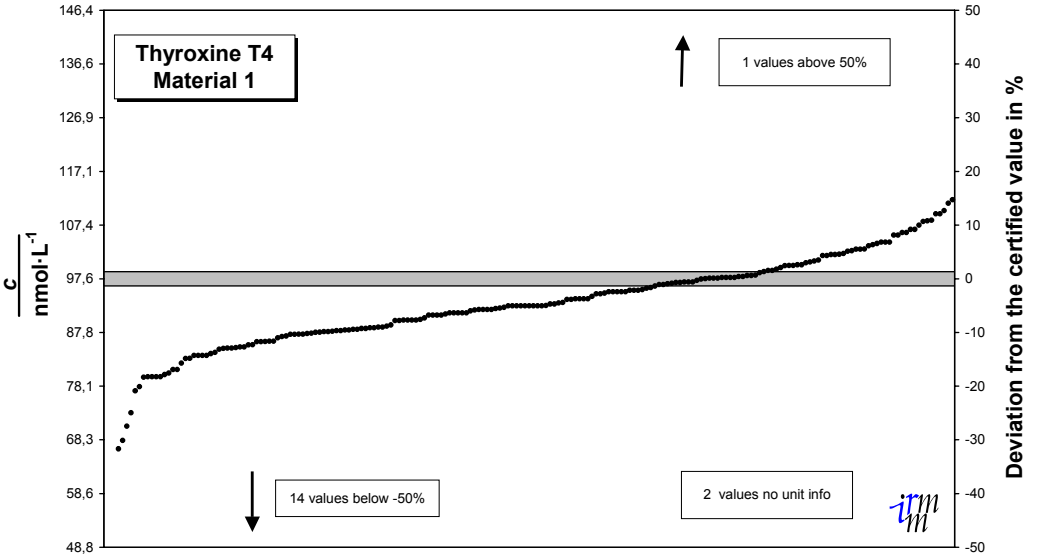

IMEP- 17: Trace and minor constituents in human serum
Certified value : 10.47 ± 0.48 g·L-1 [U=k·uc (k=2)]
IgG
Material 1
Values above 50%
c (mmol/L)
Uncertainty (mmol/L)
Dev. (%)
16.34
0
56
26.7
0
155
c
g·L-1
Deviation from the certified value in %
Results from all participants (511 laboratories)

Fig. 19

IMEP- 17: Trace and minor constituents in human serum

Certified value : 97.6 ± 1.3 nmol·L^{-1} [$U = k \cdot u_c$ (k=2)]

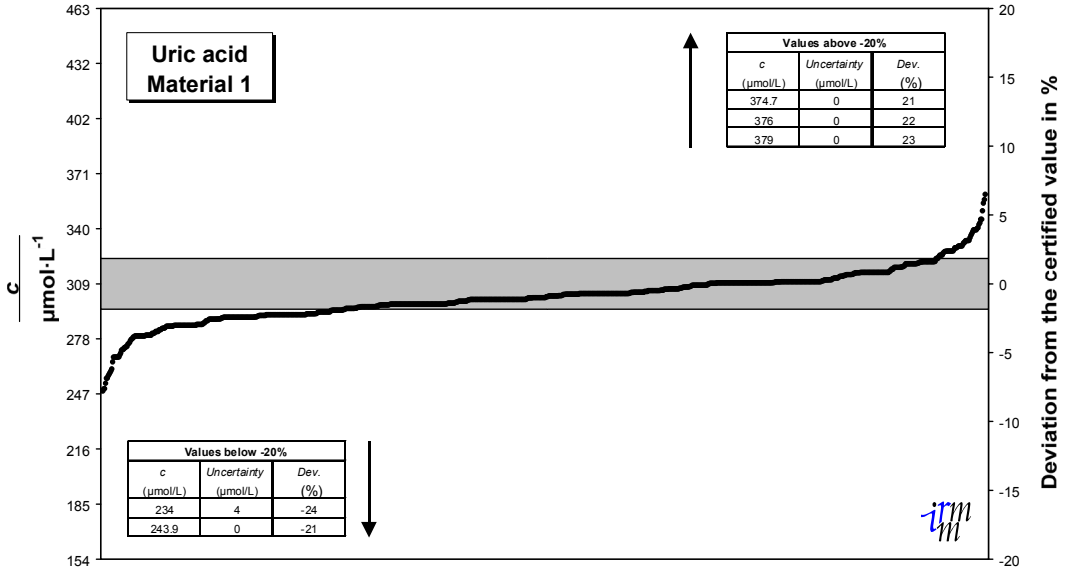


Results from all participants (221 laboratories)

Fig. 20

IMEP- 17: Trace and minor constituents in human serum

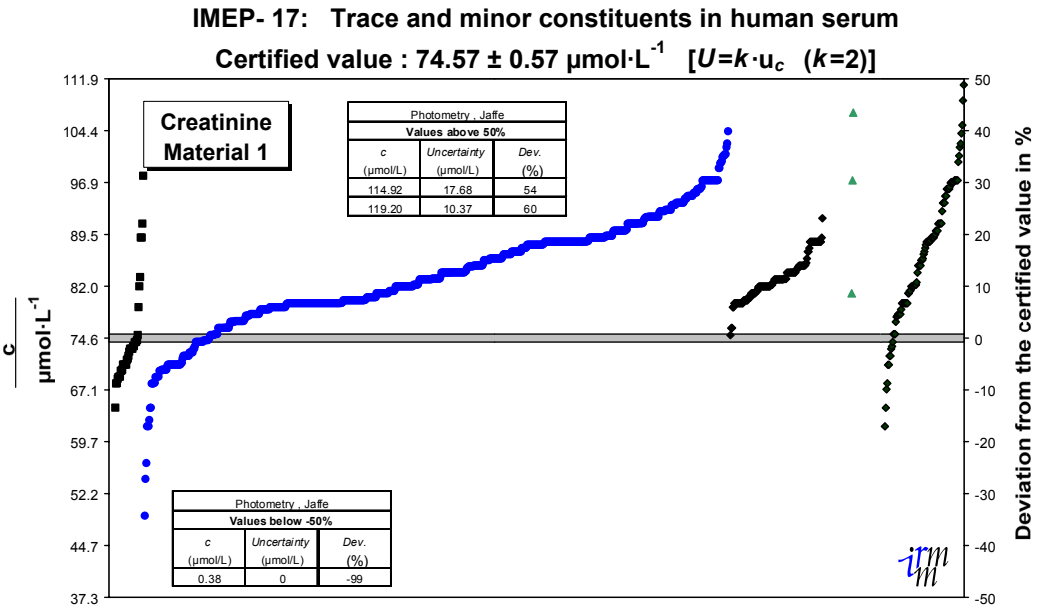
Certified value : 308.9 ± 5.7 µmol·L^{-1} [$U = k \cdot u_c$ (k=2)]



Results from all participants (993 laboratories)

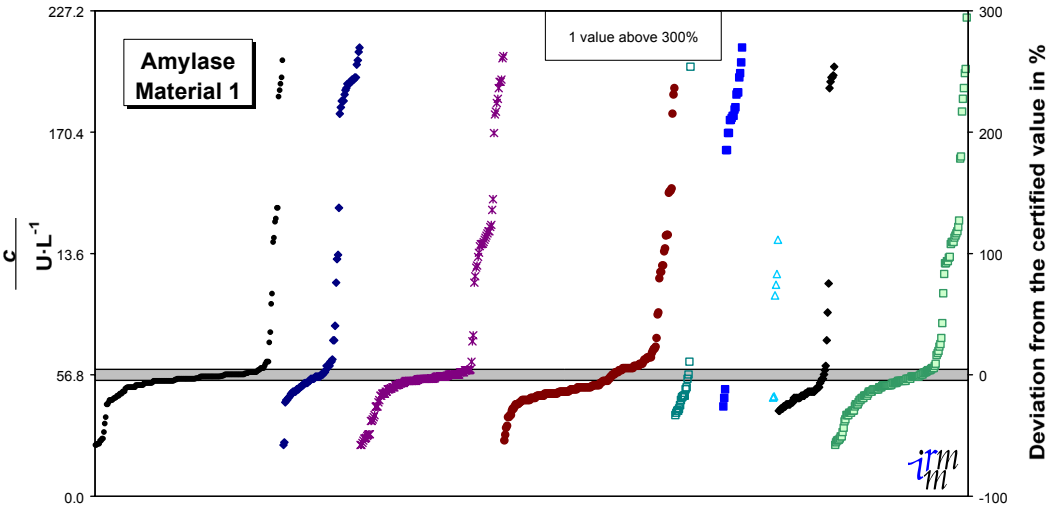
IMEP-17
Participants' results.
Graphs by method group and component

Fig. 21



All reported results (1022) arranged in method groups: Photometry, enzymatic; Photometry, Jaffe; Vitros 250-950; Vitros DT60 and Other/No info

Fig. 22



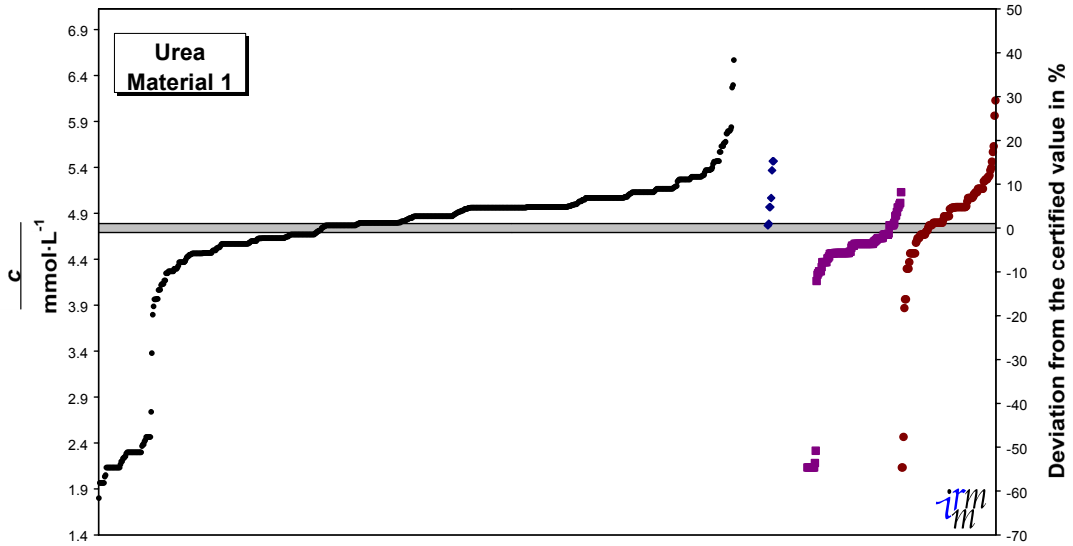
All reported results (863) arranged in method groups: IFCC comparable methods; Different methods, Scandinavian level; Different methods, Roche level; Different methods, Original level; Vitros 250-950, calculated to IFCC; Vitros 250-950, Scandinavian level; Vitros 250-950, calculated to Roche level; Vitros 250-950, original level and Other/No info

The method groups indicated in the legends are displayed from left to right

Fig. 23

IMEP- 17: Trace and minor constituents in human serum

Certified value : 4.772 ± 0.049 mmol·L^{-1} [$U=k\cdot u_c$ (k=2)]

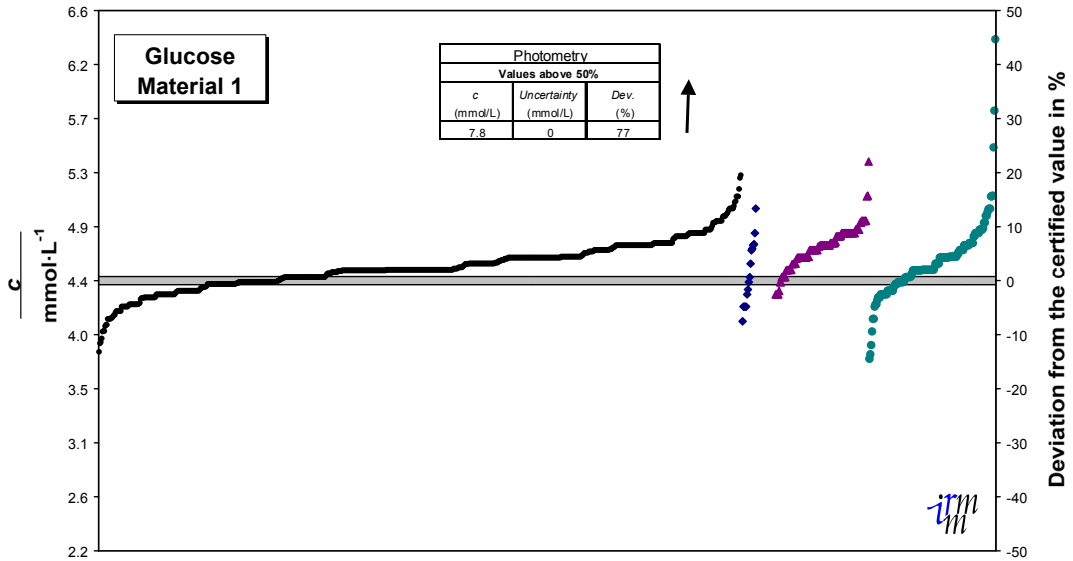


All reported results (1004) arranged in method groups: Photometry, enzymatic; Photometry, chemical; Vitros 250-950 and Other/No info

Fig. 24

IMEP- 17: Trace and minor constituents in human serum

Certified value : 4.412 ± 0.033 mmol·L^{-1} [$U=k\cdot u_c$ (k=2)]



All reported results (1011) arranged in method groups: Photometry; Amperometry; Vitros 250-950 and Other/No info

The method groups indicated in the legends are displayed from left to right

Fig. 25

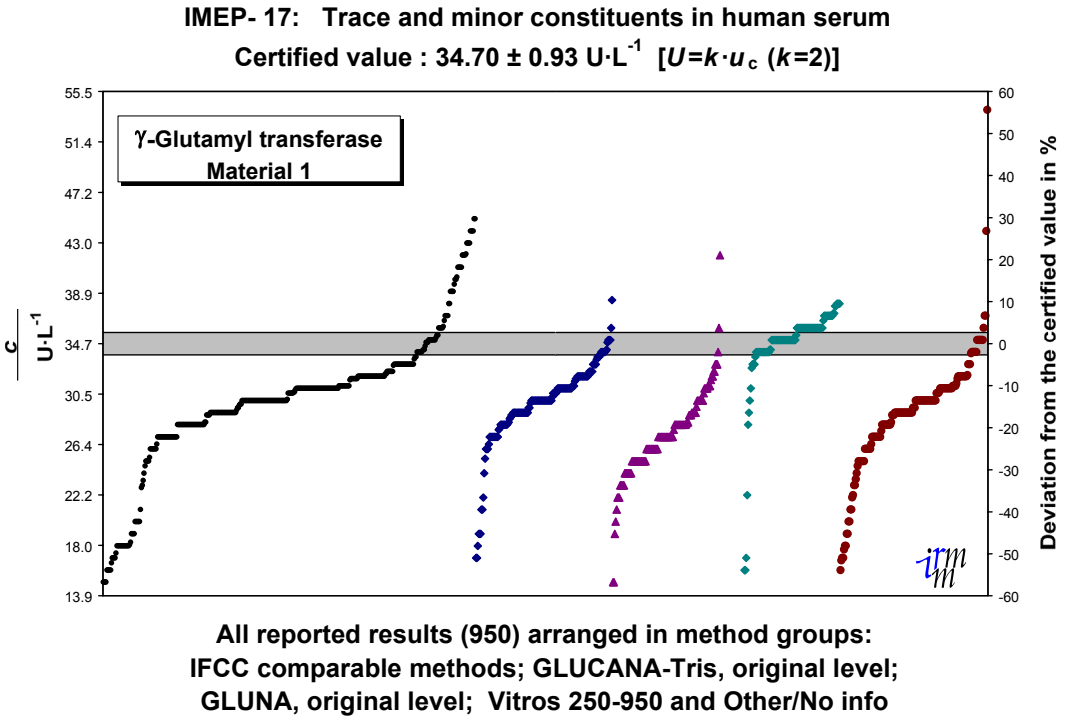
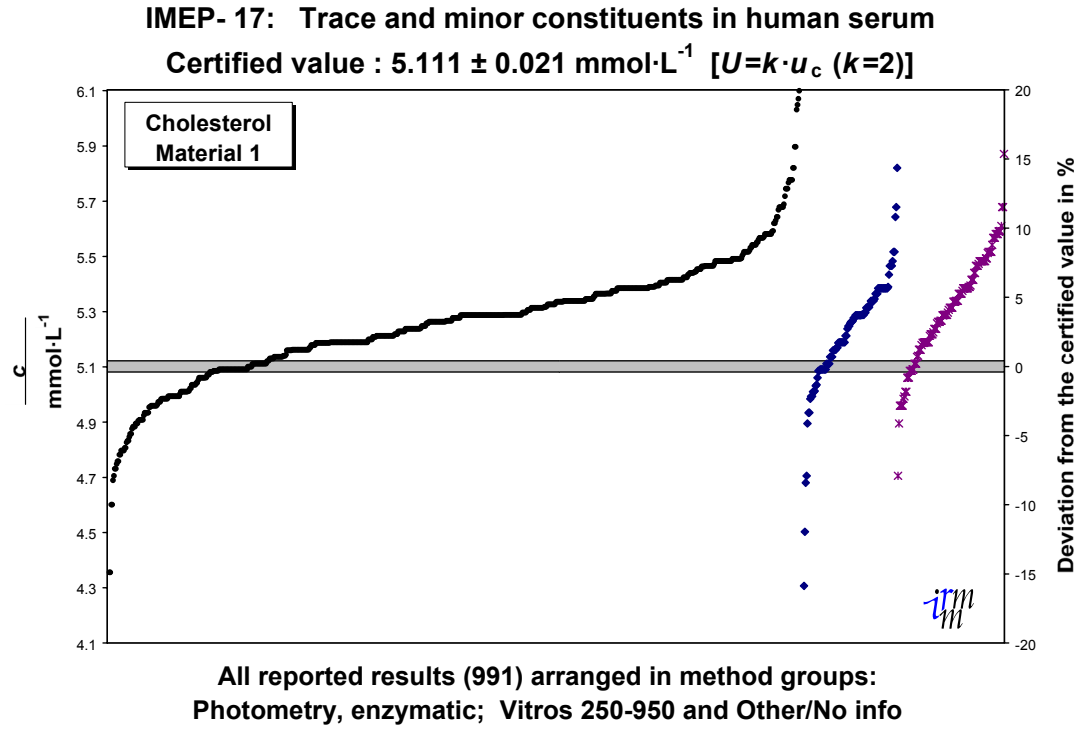


Fig. 26



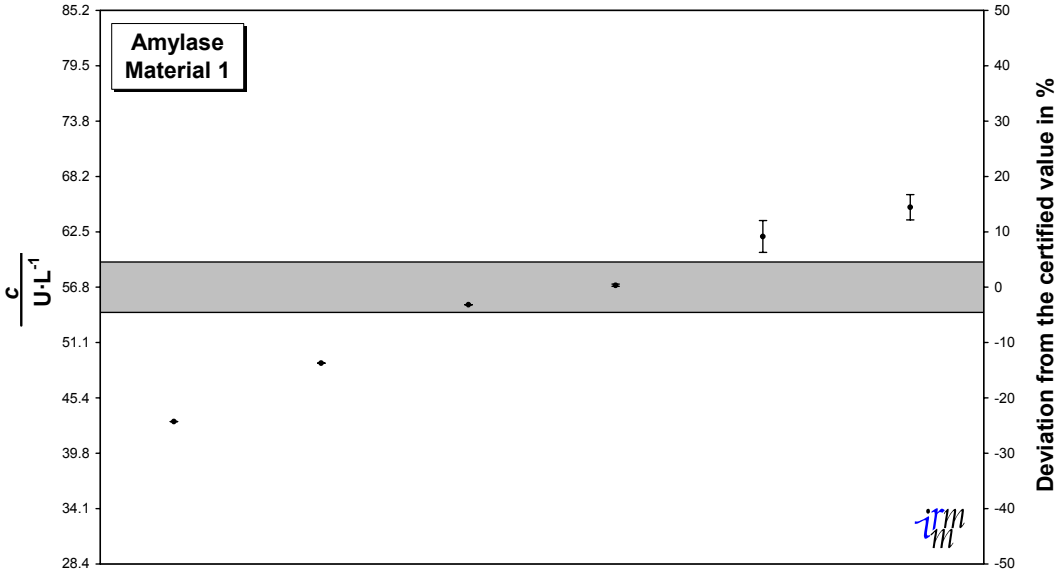
The method groups indicated in the legends are displayed from left to right

IMEP-17
Participants' results.
Country/regional graphs by component

Fig. 27

IMEP- 17: Trace and minor constituents in human serum

Certified value : 56.8 ± 2.6 U·L^{-1} [$U=k\cdot u_c$ (k=2)]

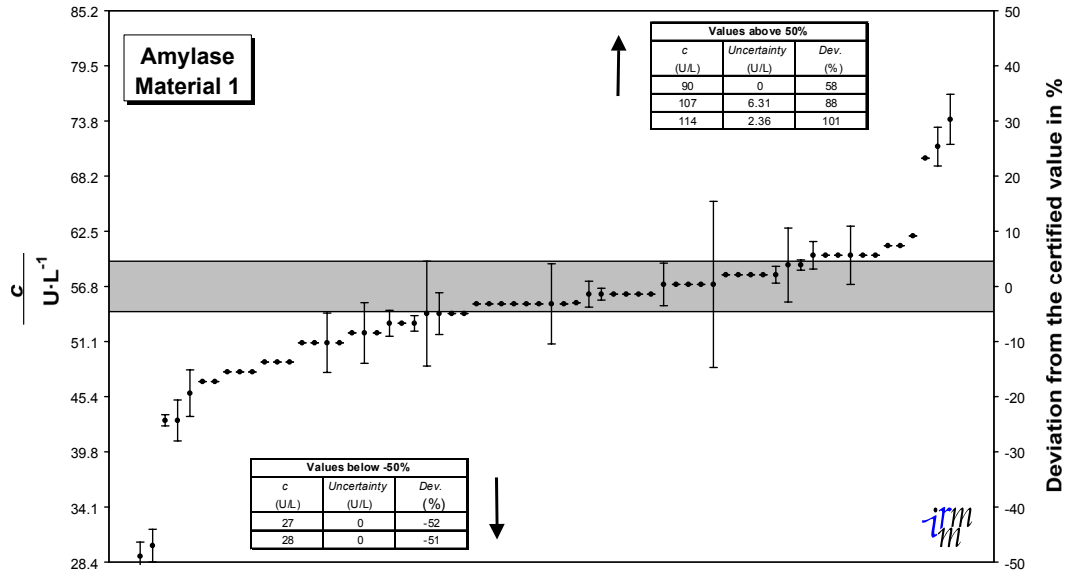


Results from participants from Africa; South Africa

Fig. 28

IMEP- 17: Trace and minor constituents in human serum

Certified value : 56.8 ± 2.6 U·L^{-1} [$U=k\cdot u_c$ (k=2)]

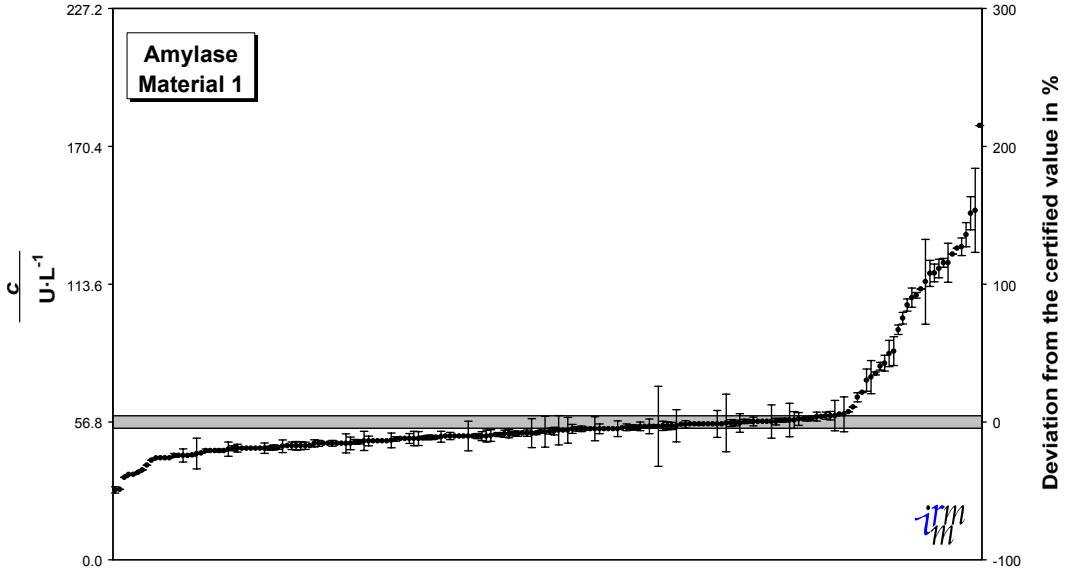


Results from participants from Asia-Pacific; Australia, China and New Zealand

Fig. 29

IMEP- 17: Trace and minor constituents in human serum

Certified value : 56.8 ± 2.6 U·L^{-1} [$U=k\cdot u_c$ (k=2)]

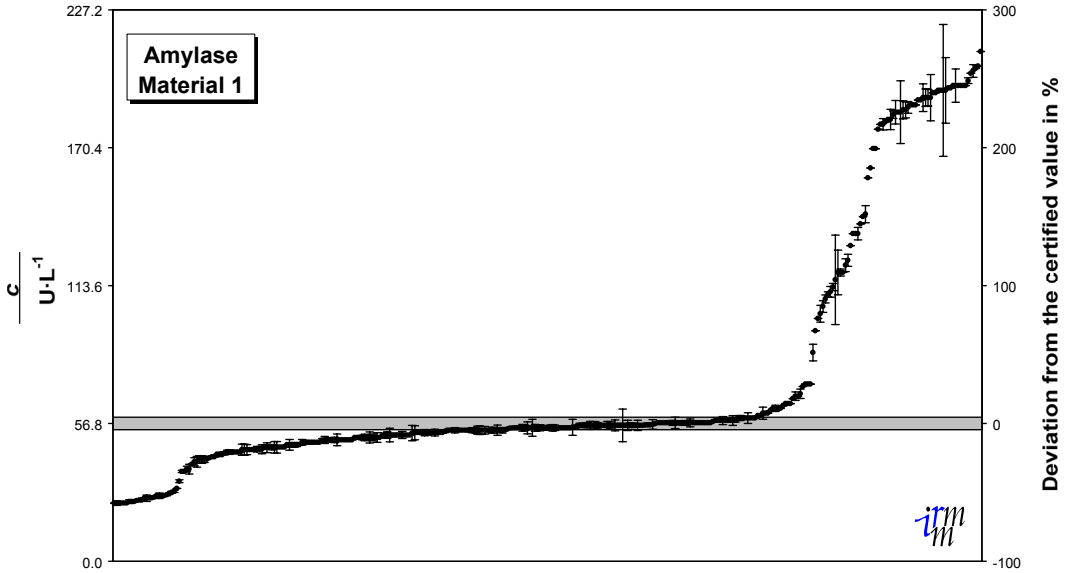


Results from participants from EU Candidate Countries; Bulgaria, Cyprus, Czech Republic, Estonia, Hungary, Poland, Romania, Slovak Republic, Slovenia and Turkey

Fig. 30

IMEP- 17: Trace and minor constituents in human serum

Certified value : 56.8 ± 2.6 U·L^{-1} [$U=k\cdot u_c$ (k=2)]



Results from participants from EU Countries; Austria, Belgium, Denmark, Finland, Germany, Italy, Portugal, Spain, Sweden, The Netherlands and United Kingdom

Fig. 31

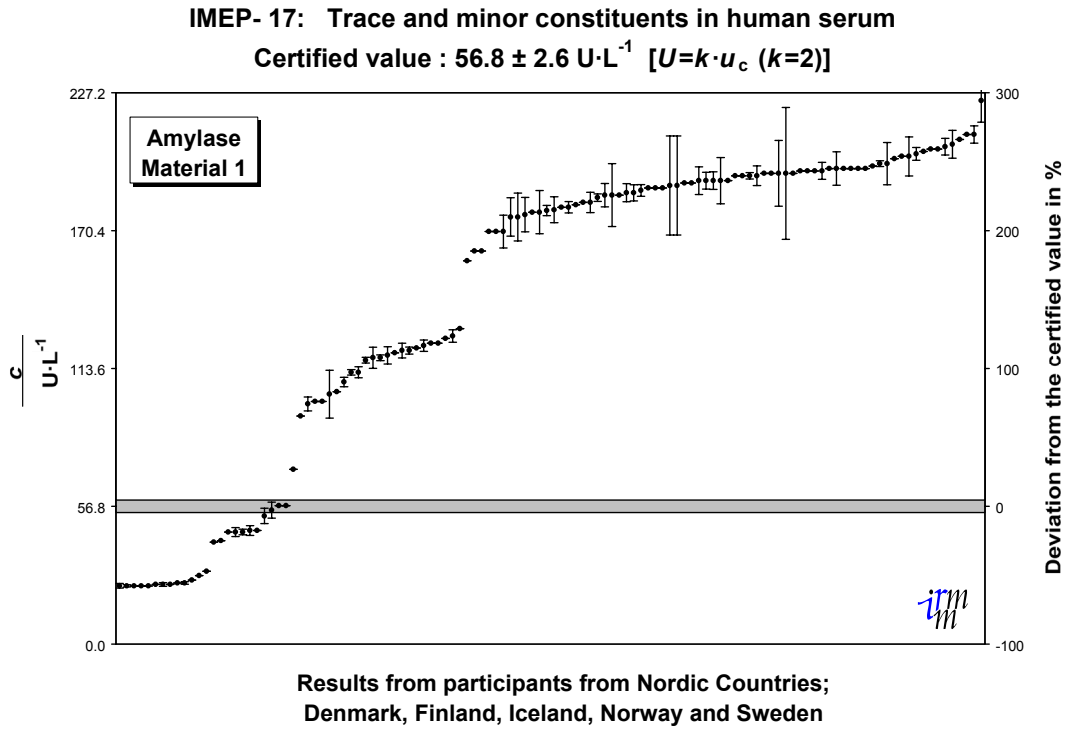

IMEP- 17: Trace and minor constituents in human serum
Certified value : 56.8 ± 2.6 U·L-1 [U=k·uc (k=2)]
Amylase
Material 1
227.2
170.4
113.6
56.8
0.0
300
200
100
0
-100
c / U·L-1
Deviation from the certified value in %
irm
Results from participants from Nordic Countries;
Denmark, Finland, Iceland, Norway and Sweden

Fig. 32

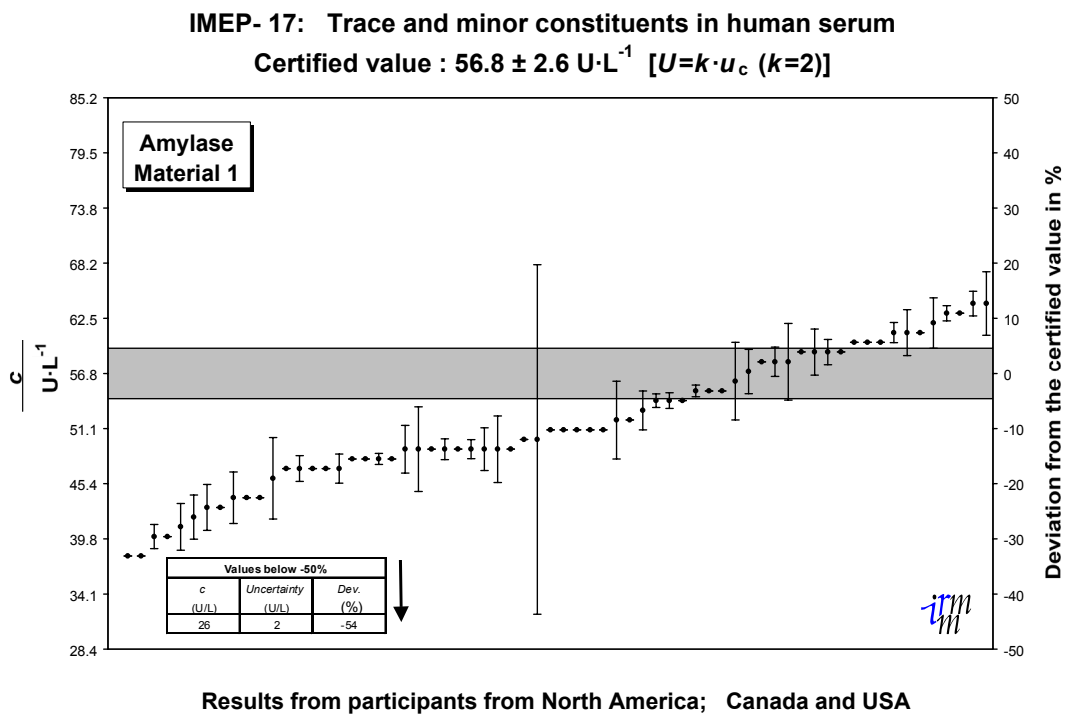
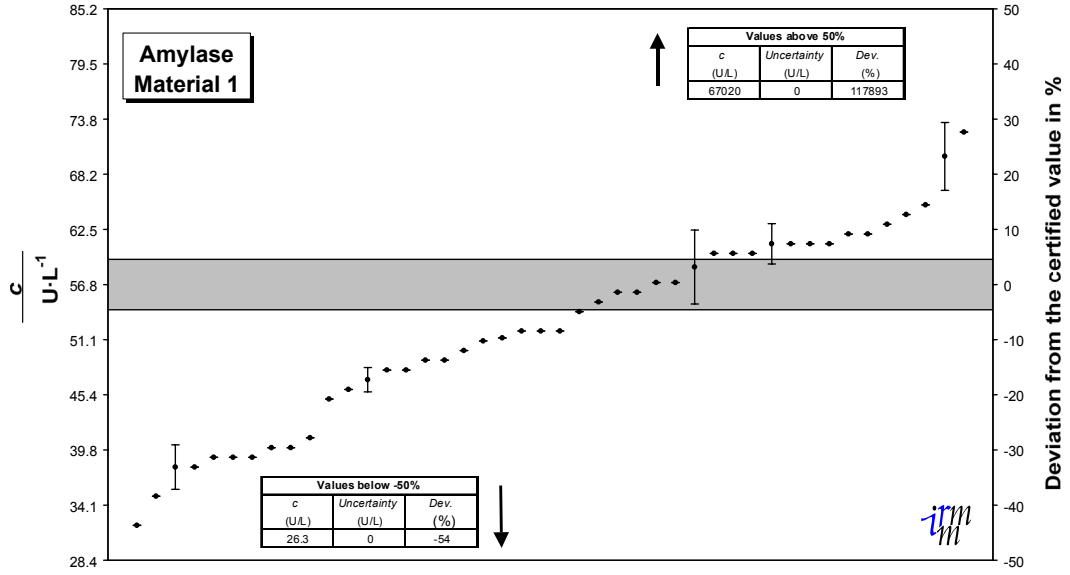

IMEP- 17: Trace and minor constituents in human serum
Certified value : 56.8 ± 2.6 U·L-1 [U=k·uc (k=2)]
Amylase
Material 1
85.2
79.5
73.8
68.2
62.5
56.8
51.1
45.4
39.8
34.1
28.4
50
40
30
20
10
0
-10
-20
-30
-40
-50
c / U·L-1
Deviation from the certified value in %
Values below -50%
c (U/L)
Uncertainty (U/L)
Dev. (%)
26
2
-54
irm
Results from participants from North America; Canada and USA

Fig. 33

IMEP- 17: Trace and minor constituents in human serum

Certified value : 56.8 ± 2.6 U·L^{-1} [$U=k\cdot u_c$ (k=2)]

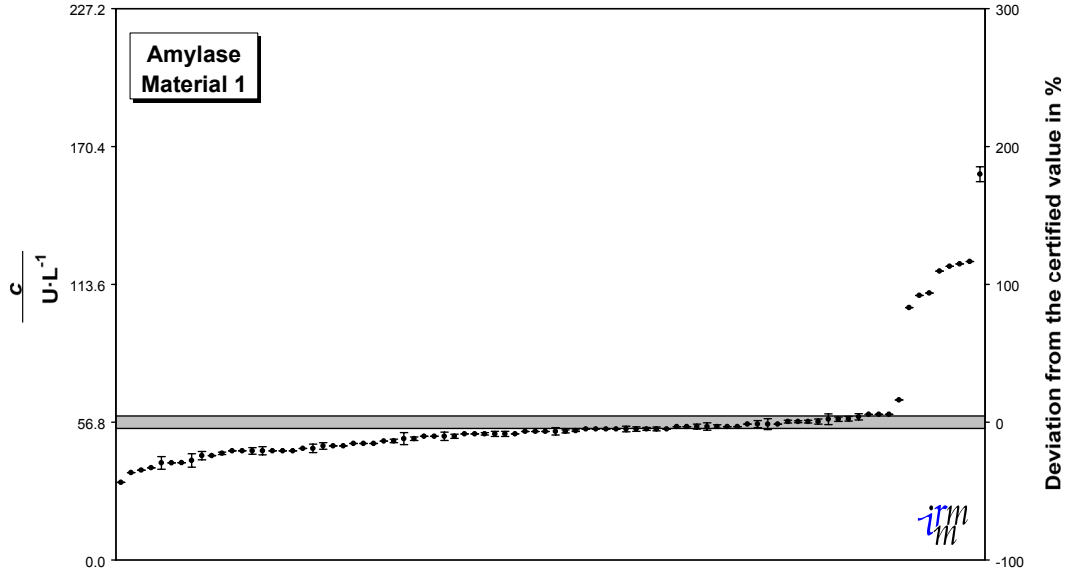


Results from participants from South + Central America; Argentina and Mexico

Fig. 34

IMEP- 17: Trace and minor constituents in human serum

Certified value : 56.8 ± 2.6 U·L^{-1} [$U=k\cdot u_c$ (k=2)]



Results from participants from Albania, Croatia, Israel and Yugoslavia

Fig. 35

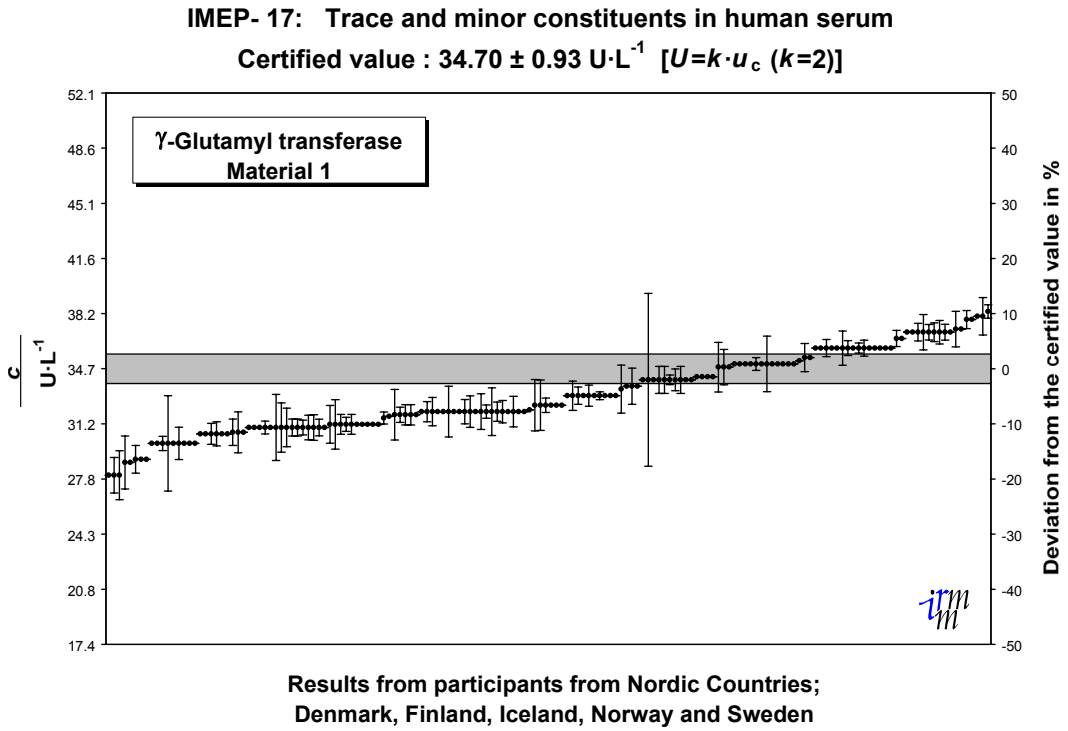

IMEP- 17: Trace and minor constituents in human serum
Certified value : 34.70 ± 0.93 U·L-1 [U=k·uc (k=2)]
γ-Glutamyl transferase
Material 1
c / U·L-1
Deviation from the certified value in %
52.1
48.6
45.1
41.6
38.2
34.7
31.2
27.8
24.3
20.8
17.4
50
40
30
20
10
0
-10
-20
-30
-40
-50
irmm
Results from participants from Nordic Countries;
Denmark, Finland, Iceland, Norway and Sweden

Fig. 36

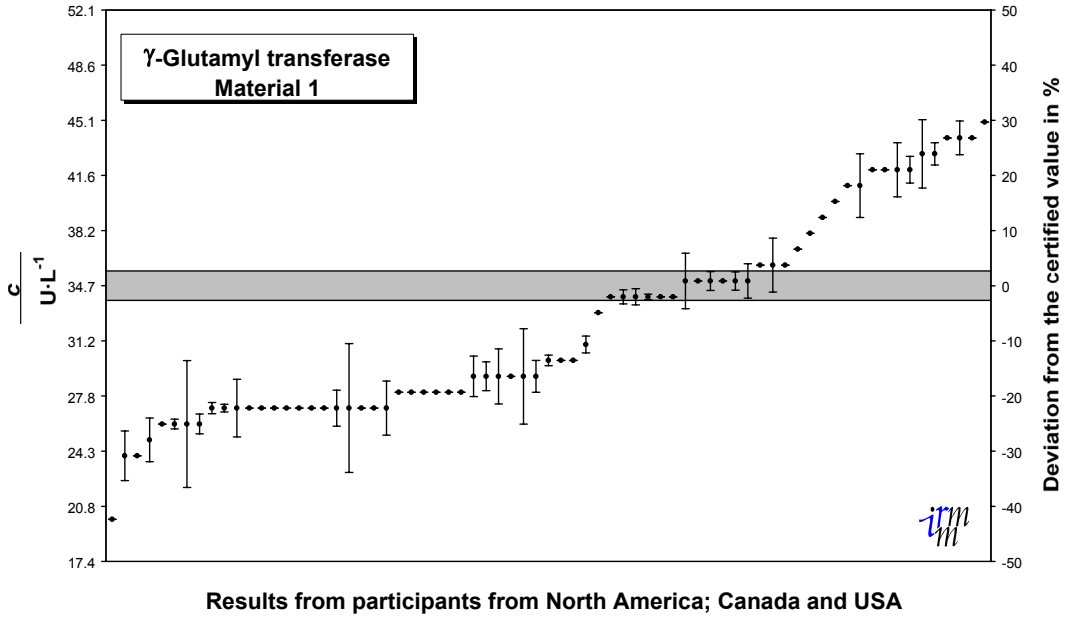
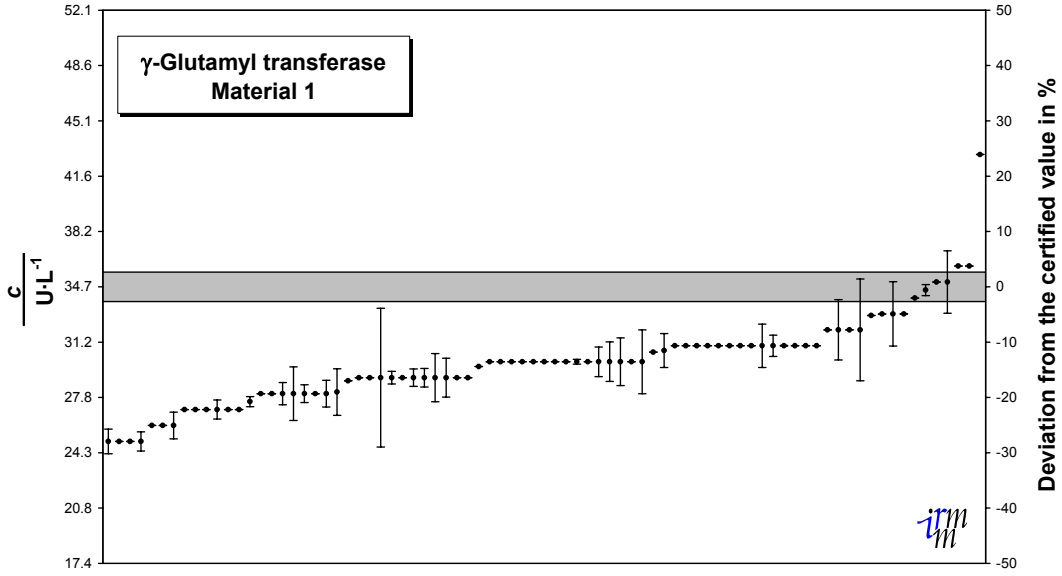

IMEP- 17: Trace and minor constituents in human serum
Certified value : 34.70 ± 0.93 U·L-1 [U=k·uc (k=2)]
γ-Glutamyl transferase
Material 1
c / U·L-1
Deviation from the certified value in %
52.1
48.6
45.1
41.6
38.2
34.7
31.2
27.8
24.3
20.8
17.4
50
40
30
20
10
0
-10
-20
-30
-40
-50
irmm
Results from participants from North America; Canada and USA

Fig. 37

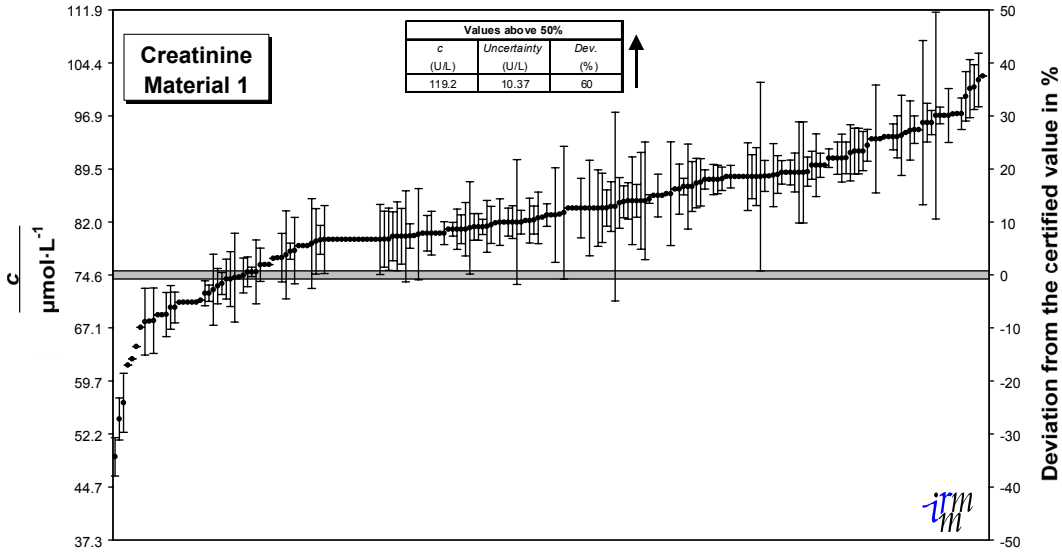
IMEP- 17: Trace and minor constituents in human serum
Certified value : 34.70 ± 0.93 U·L^{-1} [$U=k\cdot u_c$ (k=2)]



Results from participants from Asia-Pacific; Australia, China and New Zealand

Fig. 38

IMEP- 17: Trace and minor constituents in human serum
Certified value : 74.57 ± 0.57 µmol·L^{-1} [$U=k\cdot u_c$ (k=2)]

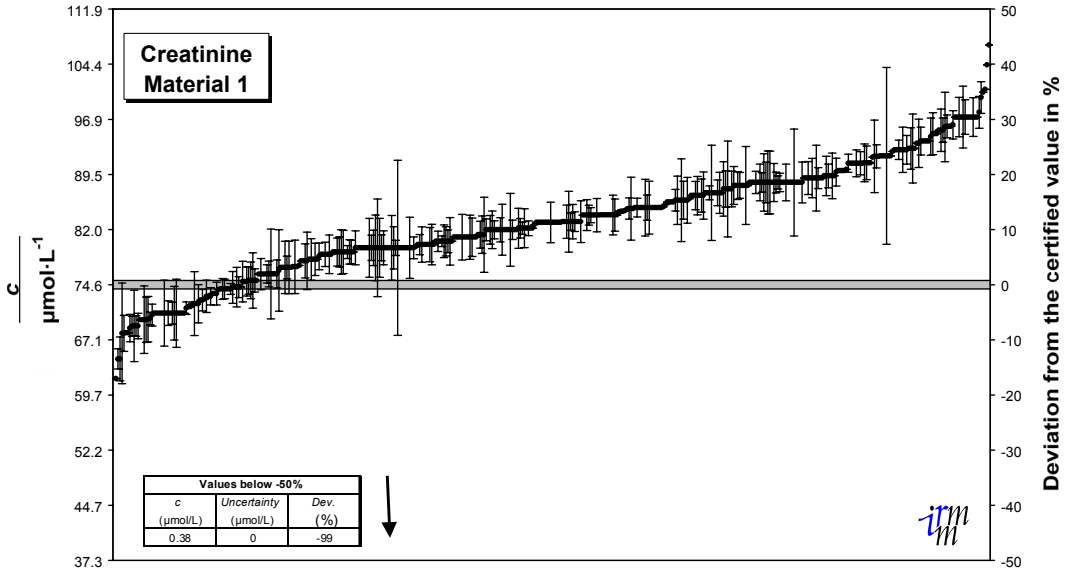


Results from participants from EU Candidate Countries; Bulgaria, Cyprus, Czech Republic, Estonia, Hungary, Poland, Romania, Slovak Republic, Slovenia and Turkey

Fig. 39

IMEP- 17: Trace and minor constituents in human serum

Certified value : 74.57 ± 0.57 µmol·L^{-1} [$U=k\cdot u_c$ (k=2)]

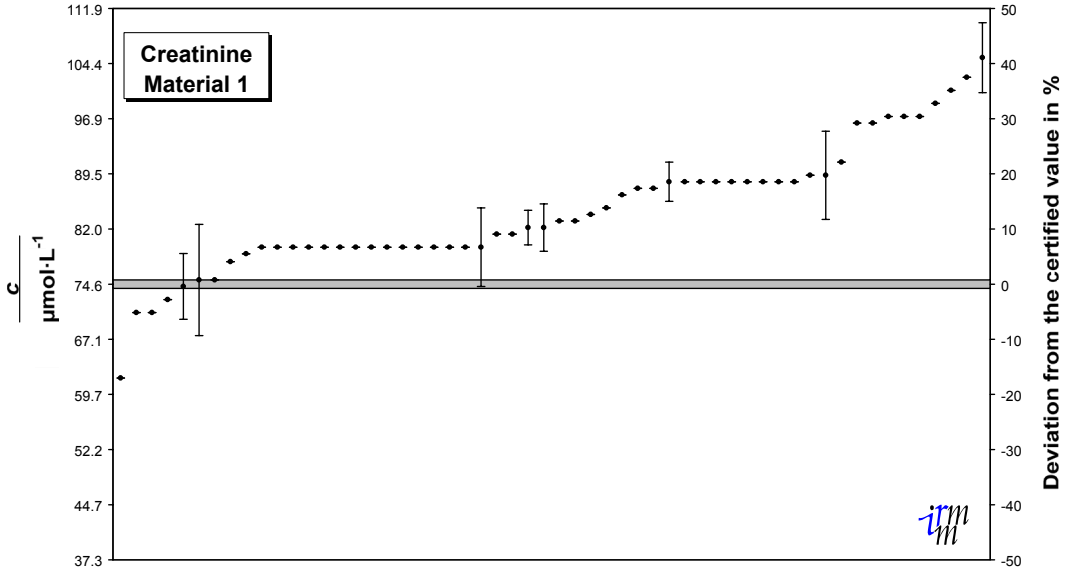


Results from participants from EU Countries; Austria, Belgium, Denmark, Finland, Germany, Italy, Portugal, Spain, Sweden, The Netherlands and United

Fig. 40

IMEP- 17: Trace and minor constituents in human serum

Certified value : 74.57 ± 0.57 µmol·L^{-1} [$U=k\cdot u_c$ (k=2)]



Results from participants from South + Central America; Argentina and Mexico

Annex 2 - Forms, letters and documents

The following official documents can be obtained from IRMM and will be attached to Part 2 of the report [21]. They constitute the information sent to coordinators and participants.

- IRMM Letter IM/L/70/01 of 4 December 2001. Invitation to EQA scheme organisations and contacts.
- Appendix 1 to Letter IM/L/70/01. Information for regional co-ordinators and participating laboratories about the test materials' properties.
- Appendix 2 to Letter IM/L/70/01. Tasks and guidelines for EQAS organisations and individuals acting as national/regional co-ordinators in IMEP-17.
- Appendix 3 to Letter IM/L/70/01. Reply form for invited EQAS organisations/co-ordinators.
- Appendix 4. Result report form.
- Certificate, IMEP-17 Certified reference values - Material 1, IM/L/062/02, IRMM, Belgium, September 2002.
- Certificate, IMEP-17 Certified reference values - Material 2, IM/L/063/02, IRMM, Belgium, September 2002.

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