Development of the JCTLM Database

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JCTLM Database: Laboratory medicine and *in vitro* diagnostics

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Useful links

- ILAC
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Database of higher-order reference materials and reference measurement procedures

→ **Search the database**

→ **List I : Certified Reference Materials and Reference Measurement Procedures for well-defined chemical entities or internationally recognized reference method-defined measurands.** Reference Materials and Measurement Procedures included in this category are those that provide values that are traceable to the SI units; e.g., electrolytes, enzymes, drugs, metabolites and substrates, non-peptide hormones and some proteins.

→ **List II: Reference Materials (e.g. reference materials for blood typing, coagulation factors, microbial serology, nucleic acids, and some proteins) that are value-assigned using an internationally agreed upon protocol.** The values of the measurands in the reference materials on this List are not SI-traceable and/or no internationally-recognized reference measurement procedure exist. List II also contains a group of purified substances that due to the absence of reference measurement procedures should not be directly used for calibration unless commutability is established.

JCTLM Database: Search form

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Database of higher-order reference materials and reference measurement procedures

Download all entries for a specified analyte category

Analyte Category

User requirement

Download .pdf file

Analyte keyword search for reference materials and reference measurement procedures

Analyte name

e.g. type an analyte name in part or full

Matches exactly: ○ Yes ◉ No

Analyte category

All

Matrix category

All

☐ **Reference Material**

☐ **Reference Measurement Procedure**

Search | Reset all

JCTLM Database: Search form

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Database of higher-order reference materials and reference measurement procedures

Analyte keyword search for reference materials and reference measurement procedures

Analyte name

Cholesterol

Matches exactly: ❍ Yes ⊙ No

Analyte category

Metabolites and substrates

Matrix category

Blood serum

☒ **Reference Material**

☐ **Reference Measurement Procedure**

Select at least an analyte from the list

☒ **Cholesterol**

Continue

Search

Reset all

JCTLM Database: Results of the search

Higher-order reference materials

Search criteria chosen: Higher-order reference materials; Analyte: cholesterol; Analyte category: metabolites and substrates; Matrix category: blood serum

Results of the search

Your search criteria produced 2 results

Select one or several higher-order reference materials summary descriptions amongst the following list and click on 'View' to access to more information

Select	Analyte	Analyte category	Matrix	Organization
☐	cholesterol	metabolites and substrates	human serum	HECTEF
☑	cholesterol	metabolites and substrates	human serum	NIST

Select all RMs

Deselect all RMs

View

JCTLM Database: Results of the search

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RM

-Create a .PDF file
-Modify your selection
-Refine your search
-RM no longer listed

Contact

-JCTLM Secretariat

Useful links

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Higher-order reference materials

Results of the search

Cholesterol in human serum

National Institute of Standards and Technology (NIST), United States

Name of reference material: SRM 1951a, lipids in frozen human serum

Quantity: Amount-of-substance concentration

Range of analyte certified / assigned value: 4.7109 mmol/l to 7.1554 mmol/l

Range of expanded uncertainty at a 95% level of confidence: 0.0116 mmol/l to 0.0142 mmol/l

Traceability: SI

CRM listing: List I

Cholesterol in human serum (lyophilized)

National Institute of Standards and Technology (NIST), United States

Name of reference material: SRM 909b, human serum

Quantity: Amount-of-substance concentration

Range of analyte certified / assigned value: 3.787 mmol/l to 6.084 mmol/l

Range of expanded uncertainty at a 95% level of confidence: 0.047 mmol/l to 0.077 mmol/l

Comparability assessment study among listed RMs: See summary of Comparability Assessment for Cholesterol in Human Serum CRMs on JCTLM List I at http://www1.bipm.org/utils/en/pdf/jctlm_preamble.pdf

Other relevant publication(s) : Certification process: Fresenius' J. Anal. Chem. 361:2 71-80 (1998); Method used for certification: Anal Chem 61, 1718-1723 (1989)

Traceability: SI

CRM listing: List I

RM Producer's Contact Information

NIST, United States
Website: http://www.nist.gov/srm
Email:srminfo@nist.gov
Tel: (301)975-6776
Fax: (301)948-3730

Create a .PDF file

JCTLM Database: Results of the search

Higher-order reference measurement procedures

Search criteria chosen: Higher-order reference measurement procedures; Analyte category: metabolites and substrates; Matrix category: blood serum

Results of the search

Your criteria search produced 4 results

Select one or several higher-order reference measurement procedures summary descriptions amongst the following list and click on 'View' to access to more information

Select	Procedure Name	Analyte	Analyte category	Matrix categories	Applicables Matrices
☑	DGKC definitive Method for Serum Cholesterol	cholesterol	metabolites and substrates	blood serum, blood plasma	human serum or plasma; lyophilized, fresh, or frozen
☑	CDCAbell-Kendall method for cholesterol	cholesterol	metabolites and substrates	blood serum	human serum; lyophilized, fresh, or frozen
☑	NIST definitive method for serum cholesterol	cholesterol	metabolites and substrates	blood serum	human serum; lyophilised, fresh or frozen serum
☐	U. Of Ghent reference method for cholesterol	cholesterol	metabolites and substrates	blood serum	human serum; lyophilised, fresh or frozen serum

Select all RMPs

Deselect all RMPs

View

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RMP
-Create a .PDF file
-Modify your selection
-Refine your search
-RMP no longer listed

Contact
-JCTLM Secretariat

Useful links
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Higher-order reference measurement procedures

Results of the search

CDCAbell-Kendall method for cholesterol
Cholesterol in blood serum
Applicable matrices: human serum; lyophilized, fresh or frozen serum
Measurement principles: Spectrophotometry
Citation(s): *Clin Chem*, 1986, **32**, 921-929
Comparability assessment studies: *Clin Chem*, 1990, **36**, 370-375

DGKC definitive Method for Serum Cholesterol
Cholesterol in blood serum
Applicable matrices: human serum or plasma; lyophilized, fresh or frozen
Measurement principles: ID/GC/MS
Citation(s): *Z. anal Chem*, 1976, **279**, 145-146
Comparability assessment studies: See CCQM-P6 results in CCQM-K6 Report

NIST definitive method for serum cholesterol
Cholesterol in blood serum
Applicable matrices: human serum: lyophilized, fresh or frozen serum
Measurement principles: ID/GC/MS
Citation(s): *Anal Chem*, 1989, **61**, 1718-1723
Comparability assessment studies: CCQM-K6 Final Report, *Clin Chem*, 1990, **36**, 370-375

Create a .PDF file

JCTLM Reference Materials Nominations Template (1/3)

	A	B	C	D	E	F	G	H	I
8	Unique Nomination Number	Date Nomination Filed	Analyte / Parameter				Basis for Traceability		
9			Analyte Category	Analyte Name	IUPAC/IFCC Number	List I or II?	Traceable to SI ?	Procedurally-defined (if so, name/cite procedure)	Traceable to an international (WHO or other) standard? If so name standard

	J	K	L	M	N	O	P	Q	R	S
8	Matrix		RM							
9	Matrix Category	Matrix	Identifier / Number	Name	Certifying Organization	Mode / approach used for value assignment (if not clearly stated in certificate)	Comments	Issued by NMI with Certificate	Certificate from other RM provider ?	RM listed in BIPM Database?

JCTLM Reference Materials Nominations Template (2/3)

	T	U	V	W	X	Y	Z	AA	AB	AC	AD	AE	AF
8	Quantity	Range of Analyte Certified / Assigned Value and Unit			Range of Expanded Uncertainty for Analyte Certified/Assigned Value				Information for Assessing Commutability				
9		From	To	Unit	From	To	Unit	Lev. of conf. (%)	Physical form of RM matrix	RM fortified with analyte or naturally incurred	Applicable analyte characteristics (e.g., isoform(s); free/bound, total)	Other relevant factors (list)	Citation of specific publication / reference if available

	AG	AH	AI	AJ	AK	AL	AM
8	Congruent with other critical factors in ISO 15194 (list other relevant factors)?						Additional Comments
9	Expression of Uncertainty	Justification of source of reference material	Are intended use and instructions for use available?	Are dates of authorization and revision given?	Are safety precautions listed?	Validation report available?	

JCTLM Reference Materials Nominations Template (3/3)

	AN	AO	AP	AQ	AR	AS	AT	AU	AV	AW	AX	AY	AZ
8	CRM information for publication in the JCTLM DB			Contact information for publication in the JCTLM DB						Contact Information for additional details (for review process)			
9	Hyperlink to Comparability Assessment Studies Among listed RMs	Other relevant publications	Comments	Producer name	Country	Website	email address	Phone number	Fax number	Name	email address	Phone number	How to obtain certificate ?

	BA	BB	BC	BD	BE	BF	BG
7		FOR REVIEW COMMITTEE USE					
8	Is there a sustainable source for the material?	Does RM value-assignment approach meet traceability requirements of IVDD industry and regulatory community ?	Additional Reviewer Comments	Recommended for publication in the JCTLM DB?	Review Word Document	Manufacturer Comment (in case of delisting)	Review team name
9							

JCTLM Reference Methods / Procedures Nominations Template (1/3)

	A	B	C	D	E	F	G	H	I
9	Unique Nomination Number	Analyte/Parameter			Method capable of traceability of analyte to SI or defined procedure?	Matrix			
10		Analyte Category	Analyte Name	IUPAC/IFCC Number		Matrix Category 1	Matrix Category 2	Matrix Category 3	Applicable Matrices

	J	K	L	M	N	O
9	Method/ Procedure					
10	Identifier / Number	Name	Organization that developed / validated method	Measurement Technique(s) Used	Comments 1	Comments 2

JCTLM Reference Methods / Procedures Nominations Template (2/3)

	P	Q	R	S	T	U	V	W	X	Y	Z	AA	AB
9	Quantity	Applicable Method Range of Assigned Value			Method Expanded Uncertainty Range				Method/Procedure Documentation				
10		From	To	Unit	From	To	Unit	Lev. of conf. (%)	Peer Reviewed Publication	How to obtain copy of method if literature publication is not available	CCQM Key Comparison Report	URL of the CCQM Key comparison report	Non-CCQM Interlab Comp. Report

	AD	AE	AF	AG	AH	AI	AJ
9	Congruent with other critical factors in ISO 15193 (list factors)?						Additional Comments
10	Other means of validation used ?	Credentialed by professionnal organisation ?	Measurand clearly defined ?	No known patent issues	Multiple testing sites not required to obtain a single value	Method instructions do not contain all the required items (list missing items from checklist)	

JCTLM Reference Methods / Procedures Nominations Template (3/3)

	AK	AL	AM	AN	AO	AP	AQ	AR
8				FOR REVIEW COMMITTEE USE				
9	Contact Information for Additional Details			Does Ref. Method value-assignment approach meet traceability requirements of IVDD industry and regulatory community?	Additional Reviewer Comments	Recommended for publication in JCTLM DB?	Review Word Document	Developer/Owner Comment (in case of delisting)
10	Name	email address	Phone number					

Higher-order Reference Materials

JCTLM Nomination file, Template Version 03, December 2004

New columns added (1/4)

Column position	Name of the columns
Column A	Unique Nomination Number
Column B	Date Nomination Filed
Column E	IUPAC/IFCC Number
Column F	List I or II?
Column I	Traceable to an international (WHO or other) standard? If so name standard
Column T	Quantity

Higher-order Reference Materials

JCTLM Nomination file, Template Version 03, December 2004

New columns added (2/4)

CRM information for publication in the JCTLM Database Website

Column position	Name of the columns
Column AN	Hyperlink to Comparability Assessment Studies Among listed RMs
Column AO	Other relevant publications
Column AP	Comments

Higher-order Reference Materials

JCTLM Nomination file, Template Version 03, December 2004

New columns added (3/4)

RM producer's contact information to be published on the JCTLM Database Website

Column position	Name of the columns
Column AQ	Producer Name
Column AR	Country
Column AS	Website
Column AT	Email address
Column AU	Phone number
Column AV	Fax number

Higher-order Reference Materials

JCTLM Nomination file, Template Version 03, December 2004

New columns added (4/4)

- information from the JCTLM Review Team
- not to be published on the JCTLM Database Website

Column position	Name of the columns
Column BD	Recommended for publication in the JCTLM-DB?
Column BE	Review Word Document
Column BF	Manufacturer Comment (in case of delisting)
Column BG	Review team name

Higher-order Reference Measurement Procedures

JCTLM Nomination file, Template Version 03, December 2004

New columns added (1/2)

Column position	Name of the columns
Column A	Unique Nomination Number
Column D	IUPAC/IFCC Number
Column P	Quantity
Column W	Level of confidence (%)
Column AA	URL of the CCQM Key comparison report
Column AC	URL of the non-CCQM Interlab Comp. Report

Higher-order Reference Measurement Procedures

JCTLM Nomination file, Template Version 03, December 2004

New columns added (2/2)

- information from the JCTLM Review Team
- not to be published on the JCTLM Database Website

Column position	Name of the columns
Column AP	Recommended for publication in the JCTLM DB?
Column AQ	Review Word Document
Column AR	Developer/Owner Comment (in case of delisting)
Column AS	Review team name

JCTLM Nomination files, Template Version 03, December 2004

Columns which will be searched on the Web

Higher-order Reference Materials

- Analyte Category — Column C
- Analyte Name — Column D
- Matrix Category — Column J

Higher-order Reference Measurement Procedures

- Analyte Category — Column B
- Analyte Name — Column C
- Matrix Category 1 — Column F
- Matrix Category 2 — Column G
- Matrix Category 3 — Column H

Higher-order Reference Materials

JCTLM Nomination file, Template Version 03, December 2004

Information returned on the first Web page resulting from a criteria search :

• Analyte Name	Column D
• Analyte Category	Column C
• Matrix	Column K
• Producer	Column N

Information returned on the second Web page resulting from a criteria search (1/2):

•Analyte Name	Column D
•List I or II?	Column F
•Basis for traceability	Column G, H or I
•Matrix	Column K

.../...

Higher-order Reference Materials

JCTLM Nomination file, Template Version 03, December 2004

Information returned on the second Web page resulting from a criteria search (2/2):

- **RM Identifier** — **Column L**
- **RM Name** — **Column M**
- **Quantity** — **Column T**
- **Range of Analyte certified/assigned value and unit: Column U to W**
- **Range of expanded uncertainty: Column X to AA**
- **Commutability study information** — **Column AF**
- **Comparability studie(s)** — **Column AN**
- **Other relevant publication(s)** — **Column AO**
- **Comments** — **Column AP**
- **RM producer's contact information** — **Column N, AQ to AV**

Higher-order Reference Measurement Procedures

JCTLM Nomination file, Template Version 03, December 2004

Information returned on the first Web page resulting from a criteria search :

• Analyte Name	Column C
• Analyte Category	Column B
• Matrix Categories	Column F, G, H
• Applicable Matrices	Column I
• Procedure Name	Column K

Information returned on the second Web page resulting from a criteria search (1/2):

•Analyte Name	Column C
•Applicable Matrices	Column I
•Procedure Name and/or ID	Column K and/or J
•Measurement Techniques Used	Column M

Higher-order Reference Measurement Procedures
JCTLM Nomination file, Template Version 03, December 2004

Information returned on the second Web page resulting from a criteria search (2/2):

•Peer review publication	Column X
•CCQM Key comparison Report / URL:	Column Z / AA
•Non-CCQM Interlab Comp. Report / URL:	Column AB / AC

Analyte Categories

	Analyte Category
1	Blood gases
2	Blood groupings
3	Coagulation factors
4	Drugs
5	Electrolytes
6	Enzymes
7	Metabolites and Substrates
8	Microbial serology
9	Non-electrolyte metals
10	Non-peptides hormones
11	Nucleic acids
12	Proteins
13	Vitamins and micronutrients
14	Other

JCTLM WG1 to recommend extension to list when necessary

Matrix Categories

	Matrix Category
1	High purity material
2	Calibration solution
3	Whole blood
4	Blood serum
5	Blood plasma
6	Urine
7	Other

JCTLM WG1 to recommend extension to list when necessary