

## Frequently asked Questions:

### What is (metrological) traceability?

This is a property of a measurement result or of the value of a calibrator, where it can be linked to the value of a stated reference (e.g. Certified Reference Material or Reference Measurement Procedure) by a measurement or a series of measurements all with known and stated uncertainties.

### Why is it important?

Diagnostic test kit measurement results should be comparable independent of the hospital, country or time in which they are made, to ensure that patients receive the correct diagnosis and treatment independent of the country or hospital they are in. If this is to be realized, then a traceable system of measurements is required.

### Who should ensure that IVD test kits results are traceable?

It is the responsibility of the IVD manufacturer to ensure that the calibrators they provide are traceable to available and appropriate CRMs or RMPs.

### How does the JCTLM database help IVD manufacturers?

The JCTLM database helps IVD manufacturers by identifying Certified Reference Materials or Reference Measurement Methods they can use as the basis of their traceability systems. It also identifies laboratories that provide Reference Measurement Services for the value assignment of calibrators for IVD manufacturers.

### Are all available Higher Order Reference Materials and Reference Measurement Methods listed in the JCTLM database?

No, only those that have been nominated by the Certified Reference Material producer or Reference Method developers can be reviewed and subsequently entered into the JCTLM database. Other, Reference Materials or Methods may fulfill higher metrological standards as described in ISO 15193 and 15194, but the IVD manufacturer will need to verify this.

### Where can I find further information on the JCTLM and its activities?

Further information can be found on the JCTLM website at: <http://www.bipm.org/en/committees/jc/jctlm>

#### JCTLM Secretariat

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# Are your *in vitro* diagnostic measurement results traceable to Higher Order Reference Materials, or Reference Methods?

The Joint Committee for Traceability in Laboratory Medicine



JCTLM listed Calibrators / Reference Methods

Manufacturer's Calibrator

End User's Calibrator

A database for laboratory medicine and *in vitro* diagnostics

[www.bipm.org/jctlm/](http://www.bipm.org/jctlm/)

## Requirements for traceability:

Manufacturers of diagnostic test kits sold in Europe must comply with the European Community Directive on *in vitro* diagnostic medical devices, including the requirement to ensure the traceability of their diagnostic test kit calibrators to available reference materials and measurement procedures of a higher metrological order.

## Role of the JCTLM:

In order to help manufacturers fulfil the requirements of the IVD Directive, the JCTLM has:

- Developed and maintains a database of available **certified reference materials (CRMs)** and **reference measurement methods/procedures (RMM/Ps)** that can be used by manufacturers to meet the traceability requirements of the EC Directive.
- Developed and maintains a database of **laboratories worldwide providing reference measurement services (RMSs)** for the value assignment of calibrators for the IVD industry.

The JCTLM is sponsored by the International Bureau of Weights and Measures (**BIPM**), the International Federation for Clinical Chemistry and Laboratory Medicine (**IFCC**), and the International Laboratory Accreditation Cooperation (**ILAC**).

### Finding available certified reference materials and reference measurement methods/procedures

More than 200 certified reference materials (CRMs) for about 130 measurands together with more than 125 reference measurement methods/procedures for 76 different health markers are presently listed in the JCTLM database. These have been reviewed and internationally agreed to be consistent with the criteria described in the standard ISO 15194 and 15193, respectively.

glucose in human serum	
<b>National Institute of Standards and Technology (NIST), United States</b>	
Phone: +1 301 975 6776	Email: srminfo@nist.gov
Fax: +1 301 948 3730	Web: http://www.nist.gov/srm
Name of the reference material	SRM 965a, glucose in frozen human serum
Quantity	Amount-of-substance concentration
Analyte certified/assigned value	1.918 mmol/l to 16.24 mmol/l
Expanded uncertainty (level of confidence 95%)	0.02 mmol/l to 0.19 mmol/l
Other relevant publication(s)	Method used for certification: <i>Biomed. Mass Spectrom.</i> , 1982, 9, 395-405
Traceability	SI
CRM listing	List I

progesterone in human serum	
<b>Institute for Reference Materials and Measurements (IRMM), European Union</b>	
Phone: +32 (0)14 571 705	Email: jrc-irmm-rm-sales@ec.europa.eu
Fax: +32 (0)14 590 406	Web: http://www.irmm.jrc.be/
Name of the reference material	BCR-347, progesterone in human serum
Quantity	Amount-of-substance concentration
Analyte certified/assigned value	10.13 nmol/l
Expanded uncertainty (level of confidence 95%)	0.21 nmol/l
Other relevant publication(s)	The certification of progesterone in two lyophilized serum materials CRM 347 and CRM 348, Report EUR 12282 EN, 1989
Traceability	SI
CRM listing	List I

JCTLM database entries.

### Reference Measurement Services listed in the JCTLM database are from laboratories that:

- use a reference method published in the JCTLM database,
- will be accredited as a calibration laboratory according to ISO/IEC 17025 and ISO 15195 by an ILAC full member, and
- have participated regularly in inter-laboratory comparisons.

### About the JCTLM Review Process

Review teams of experts regularly review CRMs, RMM/Ps and RMSs for entry into the database, for the following analyte categories:

- Blood gases
- Blood grouping
- Coagulation factors
- Drugs
- Electrolytes
- Enzymes
- Metabolites & Substrates
- Microbial serology
- Non-electrolyte metals
- Non-peptide hormones
- Nucleic acids
- Proteins
- Vitamins & micronutrients
- Other

### How to submit nominations for CRMs, RMM/Ps and RMSs for entry into the JCTLM Database

By emailing the JCTLM secretariat the completed nomination forms available from:

[http://www.bipm.org/utis/en/xls/WG1-P-02-F-01\\_F-02.xls](http://www.bipm.org/utis/en/xls/WG1-P-02-F-01_F-02.xls) and

<http://www.bipm.org/utis/en/xls/WG2-P-02-F-01.xls>

Calls for new nominations are made on a yearly cycle.

### How to apply for membership to the JCTLM Review Team(s)

Experts may apply for membership of a review team by emailing the JCTLM secretariat the application form available from:

<http://www.bipm.org/utis/en/doc/WG1-P-06-F-01.doc>

