

CIRME

The Centre for Metrological Traceability in Laboratory Medicine (CIRME)



UNIVERSITÀ DEGLI STUDI DI MILANO

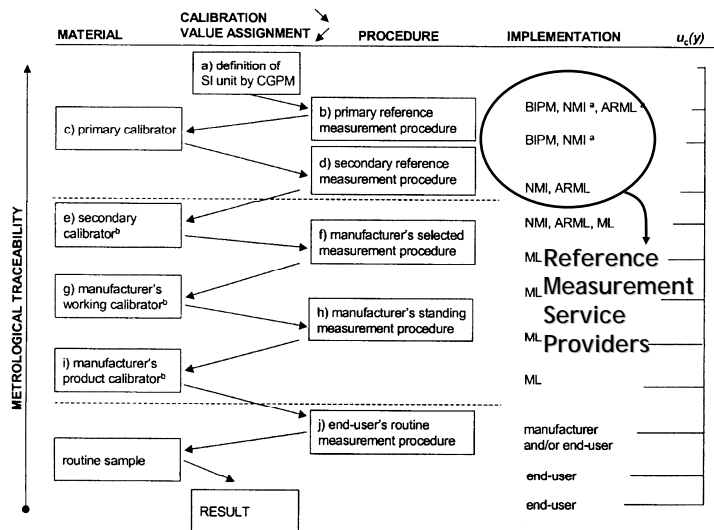
Centro Interdipartimentale per la Riferibilità Metrologica in Medicina di Laboratorio (CIRME)

created on 2006 with the scope to join in a sole entity scientists and activities of various Departments of the University of Milan interested in the development of reference methods and calibration materials of high metrological order in the field of biomedical diagnostics.

Direttore: Prof. Mauro Panteghini

sito web: <http://users.unimi.it/cirme>

Traceability implementation



CIR



UNIVERSITÀ DEGLI STUDI DI MILANO

ISO 17511:2003. In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials.

2



Reference Measurement Service Providers

Laboratories have been assessed according to the following criteria:

- metrological level of the employed reference measurement procedure (compliance with the JCTLM list).
- accreditation to ISO 17025/15195 standards (for each individual measurand as calibration laboratory) or link to a national metrology institute.
- demonstration of their competence by regular comparative measurements in specific EQAS.

CIRME



UNIVERSITÀ DEGLI STUDI
DI MILANO

3

JCTLM database : Laboratory medicine and *in vitro* diagnostics



CIRME reference measurement services in the JCTLM list

List of reference measurement services

This file was created on 29 October 2007 from the JCTLM-DB website (<http://www.bipm.org/jctlm/>)

Your search criteria: Reference measurement services; Analyte: ALT; Analyte category: Enzymes; Matrix category: -

CIRME, Italy	
Phone : +39 02 3904 2806	Contact person : Prof. Mauro Panteghini
Fax : +39 02 5031 9835	Email : mauro.panteghini@unimi.it
Analyte	alanine aminotransferase (ALT)
Material or matrix	blood serum, blood plasma
Applicable material or matrix	human serum or plasma (heparin); lyophilized, fresh, or frozen
Quantity	Catalytic activity concentration
Service measurement range	3.8 U/L to 250 U/L
Expanded uncertainty (level of confidence 95%)	(not available) to 2.0% The uncertainty of the lower limit of the measurement range is not available as this enzyme value is clinically irrelevant
Interlaboratory comparison results	RELA - IFCC External Quality assessment scheme for Reference Laboratories in Laboratory Medicine at http://www.dgkl-rfb.de:81/index.shtml Siekmann et al., <i>Clin. Chem. Lab. Med.</i> , 2002, 40 , 739-745
Measurement principle	Kinetic spectrophotometry
JCTLM reference measurement method/procedure	IFCC reference measurement procedure (37 °C) for ALT

CIRME



UNIVERSITÀ DEGLI STUDI
DI MILANO

4

CIRME reference measurement services in the JCTLM list

List of reference measurement services

This file was created on 29 October 2007 from the JCTLM-DB website (<http://www.bipm.org/jctlm/>)
 Your search criteria: Reference measurement services; Analyte: HbA1c; Analyte category: Proteins; Matrix category: -

CIRME, Italy	
Phone : +39 02 5031 8323 Fax : +39 02 5031 8391	Contact person : Prof. Andrea Mosca Email : andrea.mosca@unimi.it
Analyte	glycated hemoglobin (HbA1c)
Material or matrix	whole blood
Applicable material or matrix	human whole blood or human erythrocytes; lyophilized, fresh, or frozen
Quantity	Amount-of-substance fraction
Service measurement range	5 mmol/mol to 150 mmol/mol The lower limit of detection has been empirically determined in the laboratory
Expanded uncertainty (level of confidence 95%)	(Not applicable) to 2.0% The uncertainty of the lower limit of the measurement range is not available
Interlaboratory comparison results	RELA - IFCC External Quality assessment scheme for Reference Laboratories in Laboratory Medicine at http://www.dgkl-rfb.de:81/index.shtml IFCC Network of Reference Laboratories for HbA1c at http://www.ifccba1c.net/
Measurement principle	Quantification of specific peptides isolated and quantified by Capillary Electrophoresis and Mass Spectrometry
JCTLM reference measurement method/procedure	IFCC method for HbA1c (Two equivalent detection methods)

CIRME



UNIVERSITÀ DEGLI STUDI DI MILANO

5



SERVICES

Certification of Reference Materials



In cooperation with producers of RMs

Target-setting for EQAS



In cooperation with EQAS organizers

Validation of Diagnostic Kits/Instruments



In cooperation with manufacturers

CIRME



UNIVERSITÀ DEGLI STUDI DI MILANO

CIRME Reference Laboratories

6



EUROPEAN COMMISSION
JOINT RESEARCH CENTRE
Institute for Reference Materials and Measurements
Reference Materials Unit

Geel, 8 May 2009
JRC.D02/RKa/bt/mt/ARES(2009) 09-105/92349

Dr. Mauro Panteghini,
Laboratorio Analisi Chimico-Cliniche,
Centro Interdipartimentale di Ricerca sulla Riferibilità Metrologica in Medicina di
Laboratorio (CIRME),
Università degli Studi di Milano,
Azienda Ospedaliera Luigi Sacco - via GB Grassi 74
20157 Milano
ITALY

Subject: Listing of Laboratorio Analisi Chimico-Cliniche, Centro Interdipartimentale di Ricerca sulla Riferibilità Metrologica in Medicina di Laboratorio (CIRME) as validated supplier

CIRME



UNIVERSITÀ DEGLI STUDI
DI MILANO

7

CIRME



UNIVERSITÀ DEGLI STUDI
DI MILANO

Centro Interdipartimentale per
la Riferibilità Metrologica in
Medicina di Laboratorio
(CIRME)

Direttore: Prof. Mauro Panteghini

sito web: <http://users.unimi.it/cirme>

The Centre for Metrological Traceability in Laboratory Medicine (CIRME) - Training activities

The CIRME organizes international and national conferences on the topic of Traceability and Standardization in Laboratory Medicine and works actively to promote postgraduate specialization courses on issues concerning both Traceability and Standardization in Laboratory Medicine

 <p>UNIVERSITÀ DEGLI STUDI DI MILANO</p> <p>Centro Interdipartimentale per la Riferibilità Metrologica in Medicina di Laboratorio (CIRME)</p> <p>under the auspices of the</p>  <p>Scientific Meeting</p> <p>STANDARDIZATION OF HETEROGENEOUS ANALYTE MEASUREMENTS: THE EXAMPLE OF HEMOGLOBIN A1c</p> <p>6 November 2007</p> <p>MILANO Aula Magna - Università degli Studi Via Festa del Perdono 7</p>	  <p>UNIVERSITÀ DEGLI STUDI DI MILANO</p> <p>Centro Interdipartimentale per la Riferibilità Metrologica in Medicina di Laboratorio (CIRME)</p> <p>under the auspices of the</p>   <p>The Joint Committee for Traceability in Laboratory Medicine</p>
<p>2nd International Scientific Meeting STANDARDIZATION IN CLINICAL ENZYMOLOGY: A CHALLENGE FOR THE THEORY OF METROLOGICAL TRACEABILITY Milano, 25 Novembre 2008</p>   <p>UNIVERSITÀ DEGLI STUDI DI MILANO</p> <p>Centro Interdipartimentale per la Riferibilità Metrologica in Medicina di Laboratorio (CIRME)</p> <p>under the auspices of the</p>   <p>The Joint Committee for Traceability in Laboratory Medicine</p> <p>3rd International Scientific Meeting STANDARDIZATION OF PROTEIN BIOMARKER MEASUREMENTS: NEW INITIATIVES FOR REFERENCE MEASUREMENT SYSTEMS Milano, 17 November 2009</p>	