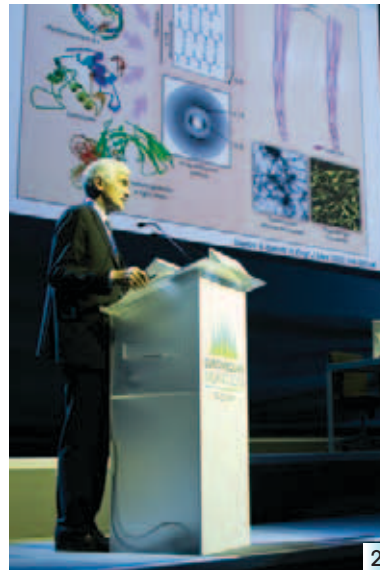


20<sup>th</sup> IFCC-EFLM European Congress of Clinical Chemistry and Laboratory Medicine  
45<sup>th</sup> Congress of the Italian Society of Clinical Biochemistry and Clinical Molecular Biology (SIBioC)

### Congress continues



1. The exhibition area



2. Plenary Lecture on Sick molecules and amyloidosis: Prof. Giampaolo Merlini

The scientific program of the second day of the Congress was also very interesting. The outstanding Plenary Lecture by Prof. Giampaolo Merlini took us into the fascinating territory of diseases caused by protein misfolding. The advances in understanding the molecular mechanisms of this pro-

cess are leading to the development of novel therapeutic strategies. By the end of Tuesday morning around 4.700 registrations were recorded. Today's program topics cover a wide range of aspects of laboratory medicine. The IFCC session on the translation of Guideline recommendations

into clinical practice is of particular importance for the everyday laboratory work. The workshop on Publication Ethics and Scientific Writing is so successful that three editions of the course have been necessary (Monday to Wednesday) to accommodate all the requests.



### CULTURAL AND SOCIAL EVENING

#### Castello Sforzesco

starting at 19:00

Tonight you will have the exclusive opportunity to feel the outstanding atmosphere of the Sforzesco Castle. Music, entertainment and a pleasant buffet will create an unforgettable event to keep in your memory.

Please present the ticket at the entrance of the castle.

#### Castello Sforzesco

Piazza Castello – 20121 Milano

#### Public transport:

Underground: MM1 Cadorna, Cairoli  
MM2 Cadorna, Lanza

Buses: 18, 50, 37, 58, 61, 94

Trams: 1, 2, 4, 12, 14, 19

### TODAY'S PROGRAMME OVERVIEW

#### 9:00 - 11:00 PARALLEL SYMPOSIA

• Room Gold  
SYMPOSIUM 9  
**BIOMARKERS OF PROSTATE CANCER**

• Room Silver  
SYMPOSIUM 10  
**NOVEL ASPECTS IN COAGULATION TESTING**

• Auditorium  
SYMPOSIUM 11  
**GASTROENTEROLOGY DISEASE IN 2013**

• Room Brown 3  
SYMPOSIUM 12  
**NEXT GENERATION SEQUENCING IN LABORATORY DIAGNOSTICS**

• Room Brown 1-2  
IFCC SESSION  
**EVIDENCE IN ACTION: TRANSLATING GUIDELINE RECOMMENDATIONS INTO CLINICAL PRACTICE**

11:45 - 12:30 **PLENARY LECTURE**  
**Molecular basis and clonal evolution of myeloproliferative neoplasm**  
R. Kralovics (Austria)

13.30 - 14.30 **POSTER WALK DISCUSSIONS**  
BONE AND JOINT DISEASES  
CARDIOVASCULAR DISEASE 1  
CARDIOVASCULAR DISEASE 2

DIABETES MELLITUS AND METABOLIC SYNDROME  
HEMATOLOGY  
HEMOSTASIS  
LIVER AND GASTROINTESTINAL DISEASES  
POINT OF CARE TESTING

#### 15:00 - 17:00 SYMPOSIUM

• Room Silver  
EFLM SESSION  
**CLINICAL GUIDELINES AND CARDIAC MARKERS**

#### 14:30 - 18:30 EDUCATIONAL WORKSHOPS

AACC  
Abbott  
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SIBioC WG on Extra Analytical Variability  
SIBioC WG on Analytical Quality  
Siemens AG Healthcare Sector  
Sysmex Europe  
Tosoh Europe  
The Binding Site Group Limited  
Thermo Fisher Scientific  
Thermo Fisher Scientific - ImmunoDiagnostics Division

#### POSTER TOPIC DISPLAYED

Bone and joint diseases  
Cardiovascular disease  
Diabetes mellitus and metabolic syndrome  
Hematology  
Hemostasis  
Liver and gastrointestinal diseases  
Point of care testing

### LAST CHANGES

**9:00 - 11:00**  
Room Gold SYM 9  
**Biomarkers of Prostate Cancer**  
M. Lazzeri is replaced by  
G. Lughezzi

**9:00 - 11:00**  
Room Brown 3 SYM 12  
**Next Generation Sequencing in Laboratory Diagnostics**  
E. Stupka is replaced by  
P. Provero

**11:45 - 12:30**  
Room Gold Plenary Lecture  
**Molecular Basis and Clonal Evolution of Myeloproliferative Neoplasm**  
F. Salvatore (Chair) is replaced  
by G. Castaldo

**16:00 - 17:00**  
Auditorium EDU W 29  
**Thermo Fisher Scientific How Biomarkers May Improve and Optimize Clinical Workflow**  
W. Fenske is replaced by  
M. Christ-Crain

## HOT SPOT IN LABORATORY MEDICINE

## Standardization and Harmonization

'Standardization' and 'Harmonization' aim to achieve not only 'the closer comparability of routine measurement results' through calibration traceability but can be applied to all aspects of the total testing procedure.<sup>1</sup> In the pre-analytical phase 'standard operating procedures' are used to reduce errors and ensure patient safety while in the post-analytical phase the use of 'harmonized or common reference intervals' provides for more consistent patient result interpretation (*Table*).

In the analytical phase diagnostic assays that are traceable to standardization and/or method harmonization are more likely to harmonize patient results. How do these processes differ?

**Standardization and metrological traceability to SI**

Standardization is a process that ensures the traceability of results to an accepted reference measurement system and greater certainty that a result is close to the true value. A reference measurement system links higher order reference methods and reference materials to routine calibrators and procedures used in clinical laboratories through an unbroken traceability chain. Ideally the harmonization of patient results is based on standardization and calibration traceability to the SI unit via a primary reference measurement procedure and primary reference material.<sup>2</sup> Once appropriate reference

materials are available these materials and the manufacturer's testing procedures can be used by industry to assign values to working and product calibrators by a value transfer process. Through this calibration process clinical laboratories will obtain standardized and traceable values, with no calibration bias among the commercial assays, e.g. cholesterol, creatinine, HbA1c.

**Method harmonization for non-SI traceable analytes**

Whereas the standardization process is traceable to SI, method harmonization is a measurement procedure that does not have traceability to the complete reference measurement system and may be biased in terms of trueness. Nevertheless, if routine assays have the same analytical specificity for a measurand, and the secondary reference materials or manufacturer's calibrators to be used for value transfer are commutable between assays, then method harmonization is feasible. For the heterogeneous protein analyte cardiac troponin I, calibration traceability to a commutable secondary reference material consisting of a pool of samples from patients with myocardial infarction will lead to improved comparability of routine troponin I results. The method harmonization procedure therefore offers a pragmatic way to harmonize test results for measurands that do not have reference measurement procedures.<sup>3</sup>

National and international efforts are required to achieve standardization and harmonization in laboratory testing. Success will require input not only from the Laboratory Medicine community but other relevant stakeholders including clinicians using laboratory tests, IT staff, patient management system vendors, regulatory bodies and consumers of laboratory testing.

**References**

- (1) Plebani M et al. Am J Clin Pathol 2011; 136:829-33.
- (2) Panteghini M. Clin Biochem Rev 2007; 28:97-104.
- (3) Thienpont LM. Clin Chem Lab Med 2008; 46:1220-2.

**Table** Requirements to achieve standardization and harmonization in laboratory testing.

Phase	Standardization/Harmonization Requirements	Vested Stakeholders
<b>Pre-analytical</b>	<ol style="list-style-type: none"> <li>1. Standardize: – Laboratory and Pre-laboratory/External pre-analytical processes.</li> <li>2. Implement SOPs to reduce error and ensure patient safety.</li> <li>3. Recommend use of evidence-based guidelines for appropriate test selection.</li> <li>4. Plan for implementation and educational phases.</li> </ol>	<ol style="list-style-type: none"> <li>1. Patients (inpatient and outpatient); healthcare practitioners e.g. phlebotomist; laboratory personnel; EFLM WG: Pre-analytical Phase.</li> <li>2. WHO World Alliance for Patient Safety; IFCC WG-LEPS;</li> <li>3. Clinicians; the pathology community; Pathology Harmony; EFLM WG:TE; guideline organisations.</li> <li>4. Professional societies; CLSI; the pathology community.</li> </ol>
<b>Analytical</b>	<ol style="list-style-type: none"> <li>1. Standardize pathology test names and units.</li> <li>2. Standardize test requesting and reporting for the EHR.</li> <li>3. Harmonize report formats where there are patient safety issues.</li> <li>4. Harmonize patient results through a standardization and/or method harmonization process.</li> <li>5. Plan for implementation and educational phases.</li> </ol>	<ol style="list-style-type: none"> <li>1-3. Clinical terminology and information systems providers; IFCC C-NPU; Governments; Industry Associations; clinicians; patient safety groups.</li> <li>4. ISO; National metrology institutes; reference material manufacturers; diagnostic assay manufacturers; IFCC scientific committees and working groups; harmonization consortium (ICHCLR); EQA organizers; clinical laboratories.</li> <li>5. Professional Colleges, other Professional Societies; CLSI; Industry Associations.</li> </ol>
<b>Post-analytical</b>	<ol style="list-style-type: none"> <li>1. Harmonize reference intervals and/or clinical decision limits where between-method bias is within allowable limits of performance and allows consistent patient result interpretation.</li> <li>2. Plan for implementation and educational phases.</li> <li>3. Requires long-term monitoring of between-method bias using commutable patient samples.</li> <li>4. Report critical patient values according to a national critical test list.</li> </ol>	<ol style="list-style-type: none"> <li>1-2. Professional Societies; IFCC C-RIDL; Pathology Harmony; the pathology community; clinicians.</li> <li>3. EQA organizers; diagnostic assay manufacturers; clinical laboratories.</li> <li>4. Laboratory personnel; patients (inpatient and outpatient); clinicians; patient safety groups; CLSI.</li> </ol>
<b>Post-post-analytical</b>	<ol style="list-style-type: none"> <li>1. Educate consumers about the meaning of laboratory tests.</li> <li>2. Develop an on-going laboratory-clinical-systems provider working relationship for long-term sustainability of pathology harmonization.</li> </ol>	<ol style="list-style-type: none"> <li>1. Patients; clinicians; consumer advocate groups; LTO.</li> <li>2. The pathology community; clinicians; systems providers.</li> </ol>

CLSI, Clinical and Laboratory Standards Institute; EFLM WG:TE, WG:Test Evaluation; EFLM WG:Pre-analytical Phase; EQA, external quality assurance; EHR, electronic health record; ICHCLR, International Consortium for Harmonization of Clinical Laboratory Results; IFCC WG-LEPS (Laboratory Errors and Patient Safety); IFCC C-NPU (Nomenclature for Properties and Units); IFCC C-RIDL (Reference Intervals and Decision Limits); ISO, International Organization for Standardization; LTO, Lab Tests Online; SOPs, standard operating procedures.

CIRME

UNIVERSITÀ DEGLI STUDI  
DI MILANOPOST-CONGRESS SATELLITE MEETINGS May 24<sup>th</sup>, 2013**Metrological traceability and assay standardization**  
Stresa, Italy

*In cooperation with the Interdepartmental Centre  
for Metrological Traceability in Laboratory Medicine, University of Milano*

TODAY!



# JOIN THE ABBOTT WORKSHOPS

## EduW 25: Current Challenges and Future Outlook in Sepsis Testing

Chair: S. Blincko (Germany), J. Bienvenu (France)  
Speakers: Frank Brunkhorst, Stefan Krüger, Stuart Blincko  
Time: Wednesday, 14:30-15:30 (Room Brown 3)

Thank you for having visited our workshops and booth!

We hope you had exciting and fruitful days at the EuroMedLab 2013 in Milan and wish you safe travels back home.

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Nr. 65



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### Molecular basis and clonal evolution of myeloproliferative neoplasm



#### R. Kralovics

CeMM Research Center for Molecular Medicine of the Austrian Academy of Sciences, Vienna, Austria; 2Department of Internal Medicine I, Division of Hematology and Blood Coagulation, Medical University of Vienna, Vienna, Austria

Excessive production of terminally differentiated myeloid cells is the hallmark of myeloproliferative neoplasms (MPN). Current classification of MPN by the World Health Organization includes nine disease entities, however, only the classical BCR-ABL negative MPN are the subject of this overview. The classical MPN include polycythemia vera (PV), essential thrombocythemia (ET), and primary mye-

lofibrosis (PMF). The discovery of a gain of function mutations of the JAK2 kinase facilitated the molecular diagnosis of MPN and also offered a target for therapeutic intervention. Although the majority of MPN patients are positive for the JAK2 exon 14 mutation (V617F), one third of patients with MPN are negative for JAK2 mutations. The MPN phenotype of JAK2-V617F negative patients has been

in some cases associated with exon 12 JAK2 mutations or mutations in the thrombopoietin receptor gene MPL but they are present only in 1-5% of the cases. Therefore, considerable effort has been exerted to identify other disease associated mutations. This review will be providing an overview of these findings and discuss the role of other genes in the pathogenesis of MPN.

#### NEWS FROM MILAN

##### EXHIBITION: LEONARDO3 – THE WORLD OF LEONARDO

March 1-July 31, 2013 Daily,  
10 am-11 pm

Sala del Re, Piazza della Scala, at the entrance of Galleria Vittorio Emanuele [http://www.leonardo3.net/index\\_eng.htm](http://www.leonardo3.net/index_eng.htm).

This show presents the results of research carried out over the last ten years by Mario Taddei and Edoardo Zanon. Its purpose is to highlight Leonardo's work not just as "artist" but

also as "engineer" and help us understand what he wrote, what he designed, the studies he made for his machines, and how he worked. Considering Leonardo's importance as an artist, however, the exhibit would be remiss not to also include several of his artistic drawings, including those he made in preparation for his fresco of the Last Supper and his never-completed Equestrian Monument to Francesco Sforza.



#### NEWS FROM AUSTRALIA

##### NEW HOPE IN DIABETES FIGHT

SIDNEY – Australian researchers identify a protein that could be harnessed to prevent or reverse type 1 diabetes.

The researchers found the protein – CD52 – plays a key role in protecting the body against excessive immune responses, and could be used to treat other autoimmune disorders such as multiple sclerosis and rheumatoid arthritis. The findings, published today in *Nature Immunology*, focuses on the role CD52 plays in suppressing the body's immune response to the specific antigens that drive autoimmune disease.

Autoimmune diseases, such as type 1 diabetes, develop when the immune system begins to attack the body's own tissues.

The protein CD52 appears to play a dominant role in controlling or suppressing immune activity in the early stages of the immune response.

#### NEWS FROM USA

##### MONSTER TORNADO DEVASTATES OKLAHOMA CITY AREA

OKLAHOMA CITY – A huge tornado cut a devastating path in suburban Oklahoma City Monday, slamming schools, a hospital, businesses and homes, and killing at least 51 people. The tornado ripped through Moore in the southern part of the Oklahoma City metropolitan area, devastating homes

and buildings. It was estimated to be at least two miles (3.2 km) wide at one point as it moved through Moore and raked the adjacent cities for 40 minutes. Areas of metropolitan Oklahoma City appeared to be in ruins after the tornado moved through the region. The preliminary rating of damage created

by the tornado is at least EF4 (winds 166 to 200 mph) – the second-most severe classification on a scale of zero to five – according to the National Weather Service. Barack Obama declared a major disaster in Oklahoma, ordering federal aid to supplement state and local recovery efforts.

### POSTER AWARDED ON TUESDAY 21 MAY

#### SPONSORED BY BIOMEDIA

##### T048

A RAPID AND SELECTIVE METHOD FOR THE MEASUREMENT OF TESTOSTERONE IN HUMAN SERUM IN 10 SECONDS USING LASER DIODE THERMAL DESORPTION-DIFFERENTIAL ION MOBILITY SPECTROMETRY-TANDEM MASS SPECTROMETRY (LDTD-DMS-MS/MS)  
M. Jarvis, E. McClure, P. Picard, S. Auger, G. Blachon, J. Botelho, Y. Wang (Canada)

##### T116

SPIDIA-RNA: FIRST EXTERNAL QUALITY ASSESSMENT FOR THE PRE-ANALYTICAL PHASE OF BLOOD SAMPLES USED FOR RNA BASED ANALYSES  
F. Malentacchi, L. Simi, C. Orlando, R. Wyrich, K. Guenther, C. Hartmann, P. Verderio, S. Pizzamiglio, C. Ciniselli, A. Tichopad, M. Kubista, S. Gelmini, M. Pazzagli (Italy)

##### T119

HOW TO PROCESS BLOOD SAMPLES FASTER IN A ROUTINE CLINICAL BIOCHEMISTRY LAB  
C. Munch Jensen (Denmark)

##### T150

A SENSITIVE AND SELECTIVE LC-ION MOBILITY-MASS SPECTROMETRIC ANALYSIS OF ALLOPREGNANOLONE AND ITS ISOMERS IN HUMAN PLASMA OR SERUM  
W. Jin, M. Jarvis, M. Weinstock, M. Altemus (USA)

##### T162

LOWER ENZYME ACTIVITIES OF METHYLENETETRAHYDROFOLATE REDUCTASE(MTHFR) IN PATIENTS WITH FIRST EPISODE PSYCHOSIS AND SCHIZOPHRENIA INDEPENDENT OF MTHFR C677T AND A1298C MUTATIONS  
T. Muftuoglu, O. Ozcan, D. Ipcioglu, A. Ates, M. Gulpepe (Turkey)

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##### T171

DEVELOPMENT OF PRELIMINARY CUT-POINTS FOR PROGRESSION FROM MILD COGNITIVE IMPAIRMENT TO ALZHEIMER'S DEMENTIA FOR THE VITROS® AB-42 AND VITROS TAU IMMUNOASSAYS  
H. Soares, I. Baburina, D. Kozo, S. Salamone, G. Green, L. DiMugno, P. Contestable, H. Zetterberg, K. Blennow (USA)

##### T192

LYMPHOCYTE SUBSETS AND ACTIVATION MARKERS IN CHILDREN WITH IMMUNODEFICIENCIES AND RECURRENT INFECTIONS  
G. Pantano, F. Tosato, G. Bucciol, M. Putti, B. Barbin, G. Marangi, M. Sanzari, M. Plebani (Italy)

##### T266

IMPLEMENTATION OF A PROFICIENCY TESTING FOR THE ASSESSMENT OF THE PREANALYTICAL PHASE OF BLOOD RNA  
F. Malentacchi, K. Guenther, P. Verderio, S.

Pizzamiglio, C. Ciniselli, A. Tichopad, M. Kubista, R. Wyrich, M. Pazzagli, S. Gelmini (Italy)

#### SPONSORED BY IRIS INTERNATIONAL

##### T288

CELIAC DISEASE DIAGNOSIS AND MONITORING: COMPARISON BETWEEN CHEMILUMINESCENCE AND ELISA ANTITRANSGLUTAMINASE AND ANTI-DEAMIDATED GLIADIN PEPTIDES MEASUREMENTS

A. Aita, D. Basso, E. Rossi, M. Pelloso, G. Guariso, C. Zambon, F. Navaglia, E. Greco, D. Bozzato, A. Padoan, P. Fogar, M. Plebani (Italy)

##### T403

GENETICALLY ENCODED PROTEASE SUBSTRATE BASED ON LANTHANIDE-BINDING PEPTIDE FOR TIME-GATED FLUORESCENCE DETECTION

J. Vuojola, M. Syrjänpää, U. Lamminmäki, T. Soukka (Finland)



POST-CONGRESS SATELLITE MEETINGS May 24<sup>th</sup>, 2013

**Pharmacogenomics and theranostics in practice**  
**Florence, Italy**

*in cooperation with the European Society of Pharmacogenomics and Theranostics*



POST-CONGRESS SATELLITE MEETINGS May 24<sup>th</sup>, 2013

**Cancer biomarkers – 2013**  
**Venice, Italy**

*in cooperation with the Italian Society of Clinical Biochemistry and Clinical Molecular Biology*

**PHOTOGALLERY**

1. The MiCo Entrance – The luminous covering know as “The Comet” is designed by Mario Bellini

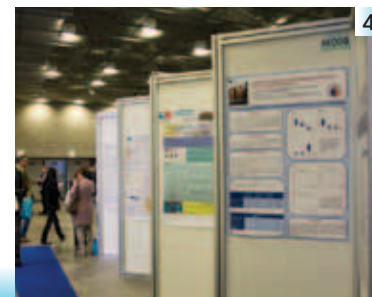


2. The Clinical Chemistry Workshop on Publication Ethics and Scientific Writing



3. The EFLM Session on “The Changing Landscape of the Clinical Evaluation of Biomarkers”

4. The Poster Area



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### invitation

#### EDUCATIONAL WORKSHOP

**How biomarkers may  
improve and optimize clinical  
workflow**

**Wednesday, May 22 | 16-17 h  
Room AUDITORIUM**

### come & see

#### INNOVATIVE BIOMARKERS

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## DO NOT MISS TOMORROW!

**Tomorrow from 11:10 to 11:40 in Room Brown 3 there will be the awarding ceremony.**

Awarded groups will be recognised in the following order:

- Milan Bursary Programme recipients
- Congress Bursary recipients
- The Binding Site Italia Awards
- Posters Awards
- IFCC-Roche Travel Scholarships

The groups of winners will be invited on stage for a group photo with the President. Names of the awarded people have been published on the final programme and will be also reported in the Thursday News



**Room Gold 12:30 - 13:00**

### CLOSING CEREMONY

- 12:30** Closing remarks
- EUROMEDLAB Milano 2013 President, *M. Panteghini (Italy)*
  - IFCC President, *G. Beastall (UK)*
  - EFLM President, *I. Watson (UK)*
- 12:50** Welcome to Paris
- EUROMEDLAB Paris 2015 Co-President and COC Chair, *B. Gouget (France)*
- 13:00** Farewell Paris Party



## The European Federation of Clinical Chemistry and Laboratory Medicine



EFLM was established in June 2007 from the merger of the Forum of European Societies of Clinical Chemistry (FESCC) and the European Communities Confederation of Clinical Chemistry (EC4). EFLM connects national clinical chemistry and laboratory medicine societies, thus creating a platform for all European laboratory medicine specialists. EFLM provides European leadership in clinical chemistry and laboratory medicine to national professional societies, to the diagnostic industry, to government, and to non-governmental organisations, in order to serve the public interest in health

care. **The EFLM represents the IFCC in Europe.** Further information at: [www.efcclm.eu](http://www.efcclm.eu)

### The EC4 Register of European Specialists in Laboratory Medicine

The EC4 Register is a database of senior professionals in the EU who meet agreed-upon education and training requirements to be independent practitioners (consultant/director grade). Over 3000 registrants from 22 countries have joined the Register since 1999. Further information at: [www.ec4register.eu](http://www.ec4register.eu)



## The Brera District

*Brera is located in the historic core of the city and it is centered around Brera street.*

Brera is home to the Brera Academy of Fine Arts and the Brera Art Gallery, which prominently contributed to the development of Brera as an artists' neighborhood and a place with a bohemian atmosphere, sometimes referred to as Milan's Montmartre. Both the academy and the gallery are housed in Palazzo Brera, the main historic building in the area. This same building also contains Milan's botanical garden as well as an astronomy observatory. Other features that contribute to Brera's character include sophisticated and romantic restaurants and bars, antique and art shops, and colorful street markets.

