



**CLINICAL MASS
SPECTROMETRY:
VALIDATION AND
ACCREDITATION OF IVD
AND LABORATORY
DEVELOPED TEST (LDT) IN
THE NEW “REGULATION
EU 2017/746” ERA**

**20-21 MAY
2023**

**VENUE:
ROME**
LA NUVOLA
CONGRESS
CENTER

ITALY



AUSPICES

The event is promoted by:



Schweizerische Gesellschaft für Klinische Chemie
Société Suisse de Chimie Clinique
Società Svizzera di Chimica Clinica
Swiss Society of Clinical Chemistry

And organized under the auspices of:



EUROPEAN FEDERATION OF CLINICAL CHEMISTRY
AND LABORATORY MEDICINE



INTRODUCTION



Dr Marco Cantù

Clinical mass spectrometry: validation and accreditation of IVD and Laboratory Developed Test (LDT) in the new “Regulation EU 2017/746” era

Over the last 10 years, mass spectrometry (MS) has become extremely popular in clinical chemistry laboratories. At the same time, there has been an evolution in regulations, standards and protocols for both validation and verification of analyses on this instrumentation (EMA, ISO, CLSI, etc.), up to the most recent European Regulation 2017/746 (IVDR).

To efficiently integrate mass spectrometry in laboratory, a clinical chemist must therefore face new challenge related to the impact of the new European Regulation 2017/746 concerning the verification and validation of analyses.

During the meeting, you will therefore acquire the skills to prepare

- Experimental designs to verify/validate an analysis in MS
- Dossiers for the national competent authority for Laboratory Developed Test (LDT) assay, in accordance with the requirements of the new European Directive IVDR 2017/746
- Dossiers for the accreditation of mass spectrometry In Vitro Diagnostic (IVD) Kit,

The meeting aims at providing participants with a complete overview of procedures and experimental designs to prepare the documentation for the analysis accreditation process (IVD & LDT) and/or for the national competent authorities inspection (LDT).

Dr Marco Cantù

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David Tonoli

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Michael Vogeser

Munich, Germany

May 20

IVDR and analytical performance

SCIENTIFIC PROGRAMME

12:00-12:45	Welcome Cocktail & Registrations
12:45-13:00	Greetings and introduction
	Chairs: Pierre-Alain Binz, Marco Cantù
	Session: "Current regulations"
13:00-14:00	Plenary Lecture: the new Regulation EU 2017/746 LDT: Validation of endogenous/exogenous molecules <i>Michael Vogeser</i>
	Session: "LDT: Validation of endogenous/exogenous molecules"
14:00-14:40	Is it really that? Analytical Specificity/Interference/matrix effect/cross reaction/carry <i>Amedeo De Nicolò</i>
14:40-15:20	How much is it? Analytical sensitivity/LOQ/measurement interval/Linearity <i>David Tonoli</i>
15:20-15:40	Coffee Break
	Chairs: Giuliana Cangemi, Christoph Seger
15:40-16:20	How far we are? Trueness/Precision/Accuracy/Recovery <i>Pierre-Alain Binz</i>
16:20-17:00	What, how, when...Preanalytic, sample manipulation, stability of reagent and sample <i>Sara Baldelli</i>
17:00-17:30	SPONSORED PRESENTATION
17:30-18:00	SPONSORED PRESENTATION
18:00	Closing day

May 21

Analytical performance & clinical performance

SCIENTIFIC PROGRAMME

- 08:30-9:00 **Chairs: Bianca Maria Goffredo, Pierre Lescuvier**
SPONSORED PRESENTATION
- **Session: “IVD: performance verification”**
- 09:00-9:40 IVD performance verification and comparison among different methods
Nora Gibitz-Eisath
- 09:40-10:20 Post validation: allerts and tips
Fabrizio Dal Piaz
- **Session: “Clinical Performance evaluation”**
- 10:20-11:00 Diagnostic sensitivity/specificity/PPV/NPV/likelihood ratio
Michel Rossier
- 11:00-11:20 Coffee Break
- Chairs: Alessio Cremonesi, Ugo De Grazia**
- 11:20-12:00 “Biological variance & Reference range” expected value
Dario Cattaneo
- 12:00-12:40 Case study: validation Protocol examples
Daniel Müller
- 12:40-13:10 SPONSORED PRESENTATION
- 13:10-13:40 SPONSORED PRESENTATION
- 13:40-13:45 Closing day
- 13:45-14:45 Light lunch

GENERAL INFORMATION

REGISTRATIONS

A limited number of places is available. All delegates must register for the congress.

To register please go to www.mzevents.it, section "Residential Events" and click on the button "Sign up online" after having selected the event from the list.

Registrations open on January 2023.

INDUSTRY EXHIBITION

An industry exhibition will be open and accessible outside the congress room, according to the times of the scientific programme.

CONGRESS LANGUAGE

The congress' official language is English.

NAME BADGE

A name badge will be required for access to the congress area. Participants will receive a name badge when they check in at the registration desk. It must be always worn.

CERTIFICATE OF ATTENDANCE

All properly registered attendees will be entitled to receive a certificate of attendance. Certificates of attendances will be sent via email after the end of the Congress.

CONGRESS VENUE

LA NUVOLA
ROMA CONVENTION GROUP
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SPONSORS





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