



**The Activities of TUBITAK UME
Chemistry Group Laboratories
in the Field of Laboratory Medicine**



JCTLM Meeting, BIPM

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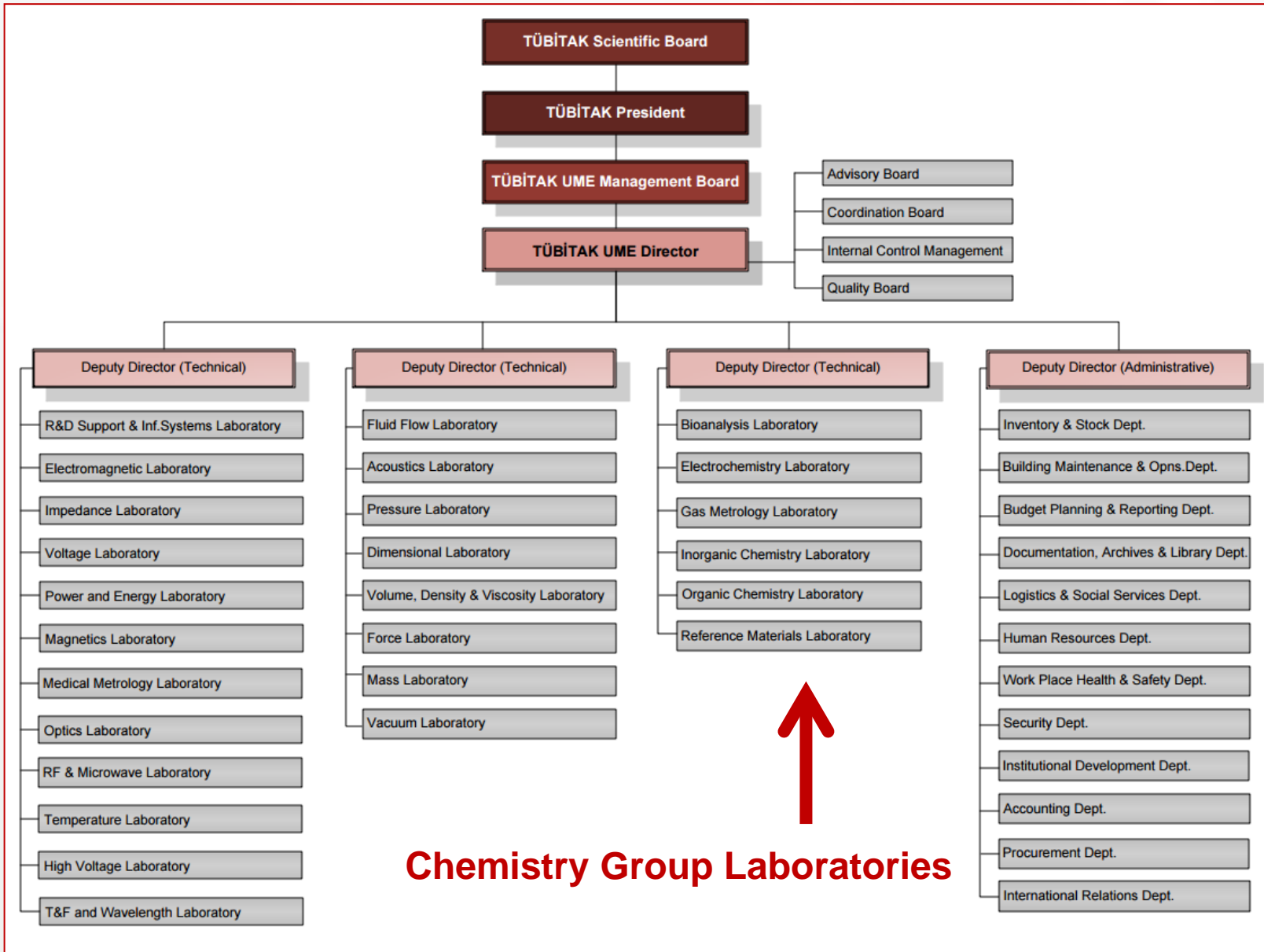
- **TUBITAK UME Organization**
- **Chemistry Group Laboratories**
- **Projects**
- **CCQM Activities**
- **JCTLM Activities**
- **Referans Materials Laboratory**
- **CRM Production Projects**

Ulusal Metroloji Enstitüsü The National Metrology Institute of Turkey



- Establishes and maintains national measurement reference standards of Turkey
- Assures traceability of measurements in trade and industry to SI units through calibration services
- Training, consulting, contracting R&D, measurement equipment production based on expertise in measurement science

TUBITAK UME Organizational Chart



Chemistry Group Laboratories



Stakeholders

- **Ministry of Health
Medicine and Clinical Instrument Department**
 - **regulations for**
 - **all clinical tests**
 - **all clinical instruments**
- **Clinical tests and instruments producers**
- **Accredited testing laboratories**
 - **require certified reference materials**
 - **proficiency testing schemes for quality control**
- **Drug and food supplement producers**
 - **need primary level measurement services to evaluate their products**




- **Metrology in Chemistry since 2001**
- **Metrology in Biology since 2010**
- **enrolled in more than 50 international comparisons in the areas of environment, food and few in clinics**
- **CMC Table**
 - **73 entries**

Bureau
International des
Poids et
Mesures

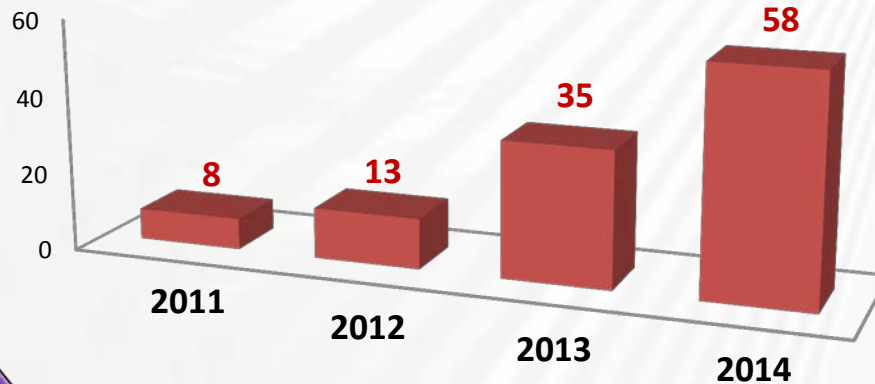
Home Key and supplementary comparisons Calibration and Measurement Capabilities - CMCs

KCDB home Version française

The BIPM key comparison database



TUBITAK UME's Number of CMCs in Chemistry



New
CMCs are
added to
the list
total
number
=73

2015

TUBITAK
UME's
Contribution
to all CMCs
in Chemistry

% 0.16

% 0.24

% 0.63

% 1.01

<http://kcdb.bipm.org/>

- **JCTLM member**
 - approved in October 2012
 - more studies in clinical area
 - **CMC Table entries**
 - 25-hydroxyvitamin D2-D3 in serum
 - calcium, potassium, magnesium in serum
 - selenomethionine in serum

OAWG

CCQM and EURAMET international measurement comparison studies in clinical area

- **CCQM-P117.a** Purity assessment of 17 β -Estradiol
- **CCQM-K55.c** Characterization of organic substances for chemical purity (Valine)
- **CCQM-K6.2** Determination of total Cholesterol in human serum
- **CCQM-K11.2** Determination of Glucose in human serum
- **CCQM-K12.2** Determination of Creatinine in human serum
- **CCQM-K132** Vitamin D in serum

IAWG

CCQM and EURAMET international measurement comparison studies in clinical area

- **CCQM-K107** Elements and Se speciation in human serum
- **EURAMET 1185** Determination of Selenomethionine in human serum

BAWG

CCQM and EURAMET international measurement comparison studies in clinical area

- **CCQM-P103.1** Measurement of multiplexed biomarker panel of RNA transcripts
- **CCQM-P58.1** Fluorescence in ELISA (stage 2)- cTnI cardiac troponin I measurement
- **CCQM-P94.2** Quantification of DNA methylation
- **CCQM-K115** Peptide purity determination - synthetic human C peptide
- **CCQM-P155** Multiple cancer cell biomarker measurement
- **CCQM-P137** Clinical amylase measurement

EMRP Projects:

- **Metallomics: Metrology for Metalloproteins, 2012-2015**
- **INFECT-MET: Metrology for monitoring infectious diseases, antimicrobial resistance, and harmful micro-organisms, 2012-2015**
- **Bio-SITrace: Traceability for biologically relevant molecules and entities, 2013-2016**

Planned EMPIR Projects - 2015:

- **JRP-h01: AntiMicroResist - Novel methods and materials for the detection, traceable monitoring and evaluation of antimicrobial resistance - LGC**
- **JRP-h07 BioIMET - A metrological platform for bio-imaging to support targeted therapies and diagnostics - LGC**
- **JRP-h08 Breath Analysis - Key reactive molecules as exhaled breath biomarkers for disease diagnostics and monitoring - IPQ**
- **JRP-h11 ReMIND - Role of metals and metal containing biomolecules in neurodegenerative diseases such as Alzheimer's disease - PTB**
- **JRP-h17: SafeBlood - Metrology support for improved surveillance of safety of blood products - PTB**

International Projects:

- **Korea-Turkey collaboration project on the development of an international standard system for the measurement of gene methylation**
 - **2016-2017**
 - **to produce and certify gene methylation CRM for cancer genes**

Our Mission

- to produce and certify reference materials
- for the **needs** of the Turkish Laboratories in the filed of
 - **Clinical**
 - **Food**
 - **Environment**

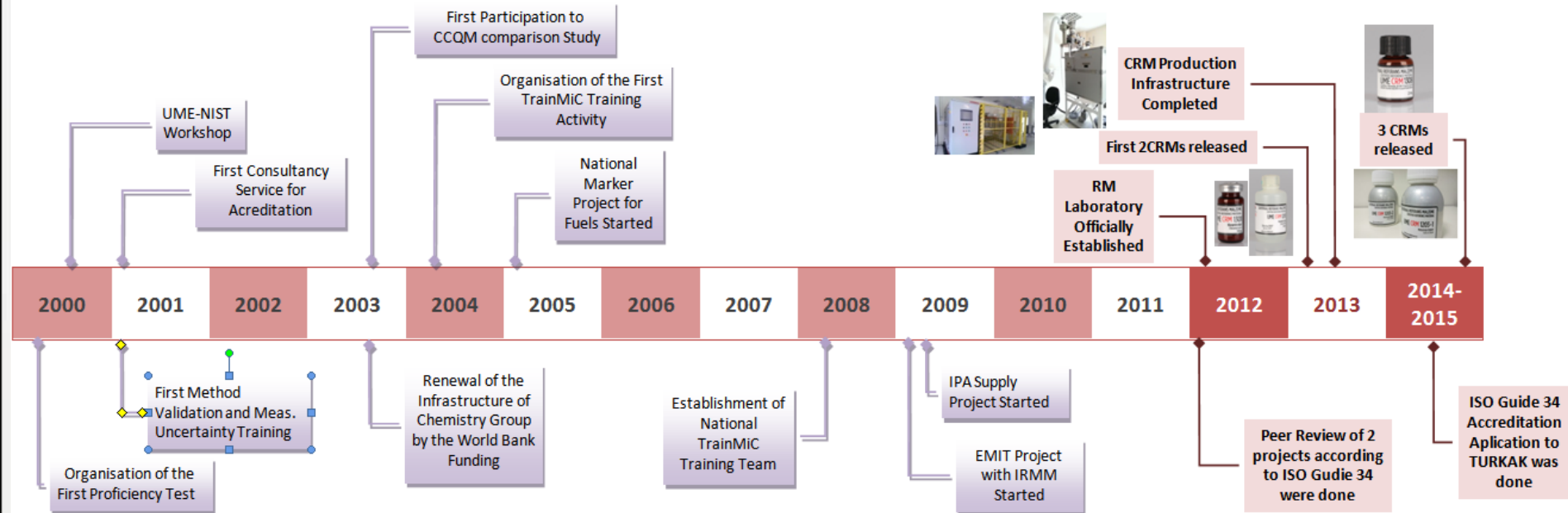


Our Activities

- Production and Certification of **Reference Materials**
- Organizing **Proficiency Tests**
- Supplying **Training** in the field of Chemical Metrology

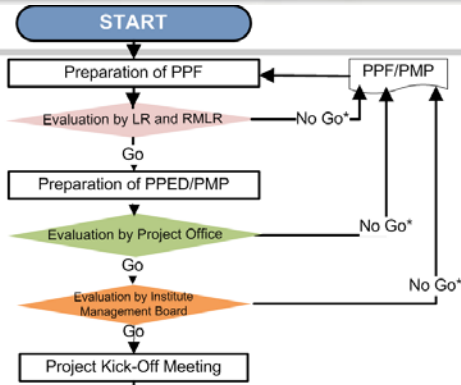


History of RM Lab.

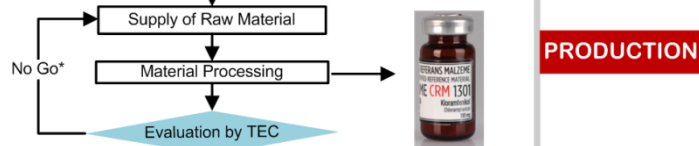


Reference Materials Laboratory

PLANNING



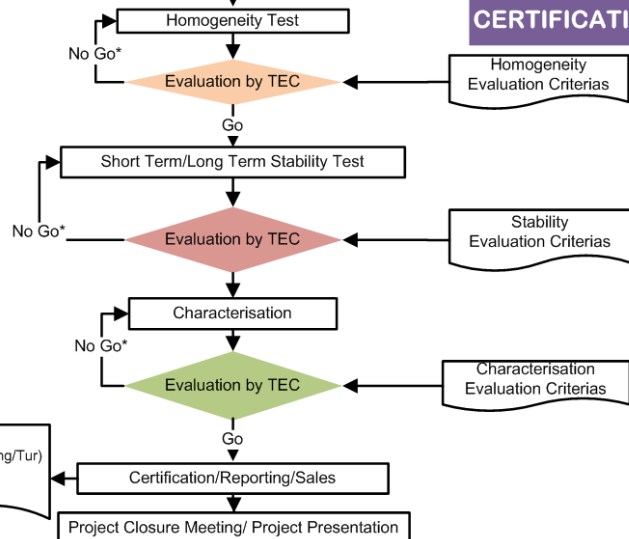
MATERIAL PROCESSING



PRODUCTION



CERTIFICATION



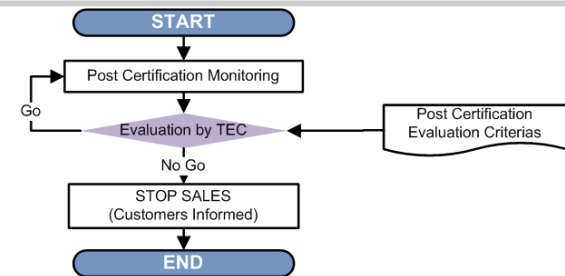
- Certificate (Eng/Tur)
- Certification Report (Eng/Tur)
- MSDS
- Final Project Report



ABBREVIATIONS:

- LR:** Laboratory Responsible
- MSDS:** Material Safety Data Sheet
- PMP:** Project Management Plan
- PPED:** Project Pre-evaluation Document
- PPF:** Project Planning Form
- RM:** Reference Materials Laboratory
- TEC:** Technical Evaluation Commity

POST-CERTIFICATION MONITORING



* "No Go" situation might end up with return to different stages of the project or with the cancellation of the project.

CRM Preparation Project:



- **Development and Production of Certified Reference Materials and Quality Control Materials for Newborn Screening and Measurements Routinely Performed by Clinical Biochemistry Labs for Amino Acids and Organic Acids, 2014-2017**
 - to produce and certify
 - 50 amino acids in human plasma
 - 50 organic acids in human urine



- **1.300.000 Newborn babies /year in Turkey**
- **new born screening test**
 - **200** babies for the **Phenylketonuria**
 - **185** babies from deficiency of **biotinidase**
 - **720** babies organic acid and amino acid problems
 - gultaric acudaria
 - fumaric aciduria etc.

Ministry of Health in Turkey

- will start a new program
- enhanced newborn screening
- for 30 different metabolic disorders

- Data obtained from Prof. Dr. Tolunay Baykal

Current CRM Production Projects:

- **25-OH Vitamin D2 and D3 in serum**
 - started in 2012
 - product is on sale
 - applied for JCTLM database recently

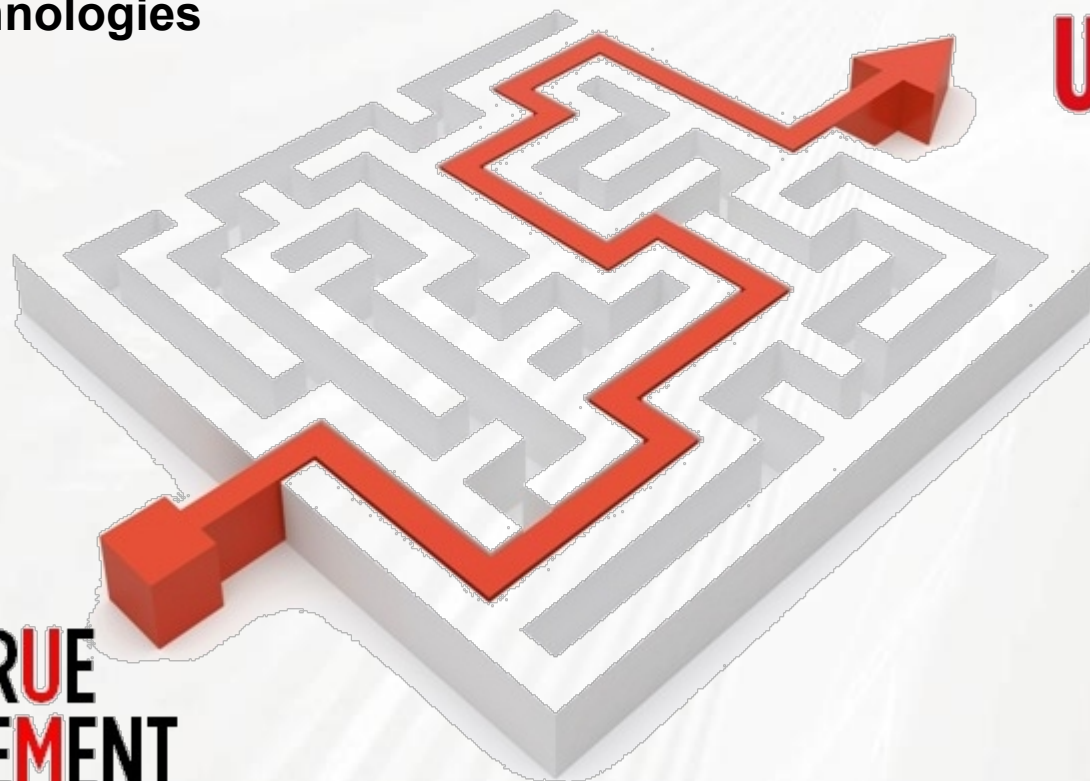
Planned CRM Production Projects:

- **Aminoacids for neonatal screening (2015-2018) started**
- **Organic acids for neonatal screening (2015-2018) started**
- **DNA Metylation RM (2016-2018)**
- **Cholesterol in serum (2016-2019)**
- **Creatinine in serum (2016-2019)**
- **Glucose in serum (2016-2019)**
- **Elements in serum (2016-2019)**
- **Hemoglobin variants in blood (2017-2020)**
- **Hormones (2018-2025)**
- **Proteins (2018-2025)**

Thank You



- Republic of Turkey, Ministry of European Union Affairs
- European Union, IPA Program
- JRC IRMM
- ZİVAK Technologies



**TRUE
MEASUREMENT
EXCELLENCE**