

## Certified reference material production in Turkey

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**Abstract:** TÜBİTAK UME, the national metrology institute of Turkey has become involved in the development of reference materials since 2000, when the first proficiency test was organized for the field laboratories. After 2009, TÜBİTAK UME has established a clean chemistry laboratory for reference measurements and state-of-the-art reference material processing and storage facilities in collaboration with EC-JRC, European Commission Joint Research Center, Belgium which is one of the world's leading developer and producer of reference materials. Accelerated with these studies, TÜBİTAK UME scientists focused on reference material production, certification and development of reference measurement techniques, giving first priority to environmental monitoring, food safety and clinical measurements. Simultaneously, the necessary procedures and documentation have been prepared and integrated to the quality management system of the institute to produce and certify reference materials according to the ISO Guide 34 (General Requirements for the Competence of Reference Material Producers). ISO Guide 34 transformed to the standard ISO 17034:2016 which requires the reference material producer to assess each of its production and testing systems, assigns an uncertainty value to all reference materials classified as "Certified Reference Material-CRM" and demonstrates traceability of measurements to SI units wherever possible. In 2016, TÜBİTAK UME has become the first reference material producer in Turkey accredited according to the ISO Guide 34. A total of 18 certified reference materials whose certifications have been completed since 2013 were included in its accreditation scope.

**Keywords:** Certified reference material; environmental monitoring; food safety; clinical measurements; accreditation; ISO 17034; ISO Guide 34 © 2017 ACG Publications. All rights reserved.

Dear Editor,

Today I would like to inform you about the recent developments in TUBİTAK UME about reference material production, certification and accreditation.

TÜBİTAK UME, the national metrology institute (NMI) of Turkey has become involved in the development of reference materials since the year 2000, when the first proficiency test was organized for the field laboratories. National marker reference materials were then produced and used to ensure the quality and security of the national marker which is added to fuel products since 2006 to control fuel smuggling in the country [1]. The motivation to produce certified reference materials according to the primary needs of Turkey initiated collaborative studies with the EC-JRC-IRMM (Belgium) which is one of the world's leading developers and producer of reference materials. Accelerated by these studies, TÜBİTAK UME scientists focused on reference material production, certification and development of primary measurement methods for material characterization. After 2009, TÜBİTAK UME has established a clean chemistry laboratory for reference measurements and state-of-the-art reference material processing and storage facilities with the aid of two projects funded by the European Union [2,3]. Simultaneously, the necessary procedures and documentation have been prepared and integrated to the quality management system of TÜBİTAK UME to produce and certify reference materials according to the ISO Guide 34 [4].

Between years 2012 and 2016, TÜBİTAK UME successfully completed 10 CRM projects yielding 18 CRMs. In the field of food safety, UME CRM 1301 “Chloramphenicol Primary Calibrant” was produced to achieve traceability in chloramphenicol residue analysis of meat, milk and milk products [5]. In the field of environmental analysis and food analysis, UME CRM 1201 “Elements in Spring Water” [6] was produced and certified for 21 elements which are toxic and nutritionally important. In the field of clinical measurements, UME CRM 1308 “25-OH Vitamin D2/D3 in Lyophilized Serum” was produced for quality control purposes in Vitamin-D analysis [7]. “Aflatoxins in Dry Fig”, UME CRM 1302 was the first certified reference material in the world which is certified for aflatoxins: Aflatoxin B1, aflatoxin B2, aflatoxin G1, aflatoxin G2 and total aflatoxin levels in dried fig matrix for validation of analytical methods [8]. “Carbon Isotope Ratio Reference Materials for “Honey (Unadulterated)”-UME CRM 1312, “Honey (Adulterated)”-UME CRM 1313, “Sucrose”-UME CRM 1309, “Glucose”-UME CRM 1310, and “Fructose”-UME CRM 1311 were produced to serve as quality control materials for the carbon isotope measurements to detect adulteration in food [9]. “Elements in Hazelnut”-UME CRM 1202 was produced to serve as a quality control material for the analysis of 11 elements and total fat in hazelnut [10]. For environmental analysis, two levels of “Sulfur in Diesel”-UME CRM 1203-1 and UME CRM 1203-2 were produced for quality control purposes [11]. Another CRM prepared for environmental analysis and monitoring was “Elements in Waste Water”-UME CRM 1204 in which 12 elements were certified [12]. In the field of quality control of fuels; “Multiparameter CRM’s for Diesel”-UME CRM 1501 and UME CRM 1502 were prepared to serve as quality control materials to verify standard methods used by the field laboratories to check quality of the produced fuels [13]. Wide application of pH measurements in different laboratories motivated the TÜBİTAK UME researchers to prepare “Certified pH 4 Buffer”-UME CRM 1401, “Certified pH 7 Buffer”-UME CRM 1402 and “Certified pH 10 Buffer”-UME CRM 1403 [14].

TÜBİTAK UME has become the first reference material producer in Turkey to be accredited according to the ISO Guide 34 standard in December 2016. A total of 18 certified reference materials whose certifications have been completed since 2013 are included in its accreditation scope.

In addition to the projects mentioned above, TÜBİTAK UME coordinates a collaborative project with a private company to produce two CRM candidates “Amino Acids in Human Plasma”, “Organic Acids in Urine” and quality control materials for newborn screening in the diagnosis of metabolic disorders affecting about 1500 babies born every year in Turkey [15]. TÜBİTAK UME also started developing of Hemoglobin A1c CRM which is used for diabetes diagnosis. TÜBİTAK UME participated to EurA1c proficiency testing program of Hemoglobin A1c which was organized by International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) throughout Europe in 2016 and 2017.

TÜBİTAK UME is the coordinator of an EMPİR (European Metrology Programme for Innovation and Research) capacity building joint research project cofounded by European Union’s H2020 research programme in collaboration with 8 partners from national metrology institutes, designated institutes and universities throughout Europe to sustainably produce “Matrix CRMs for Environmental Analysis” [16]. Three candidate reference materials; “Elements in River Water”, “Elements in Soil” and “PFOS&PFOA in Ground Water” are aimed to be produced within the scope of the project.

With their increased experience and confidence in completed CRM projects, TÜBİTAK UME scientists continue to develop and conduct new CRM projects according to the needs of the laboratories [17].

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