TÜBİTAK
ULUSAL METROLOJİ ENSTİTÜSÜ
Certificate of the Reference Material

Name of the Material : C-Reactive Protein (CRP)

Material Code : UME CRM 1008

Issue Date : 20.02.2024

Revision Date : 20.02.2024 (Revision history can be found on the last page)

Validity Period of the Certificate : 12 months from the sales date

Certified Values :
Certified Values

Parameter	Molality [1,2]	Uncertainty [2,3]	Unit
CRP	43.2	2.2	µmol/kg

[1] The certified value was determined using the amino acid analysis method involving Isotope Dilution Liquid Chromatography/High-Resolution Mass Spectrometry (ID-LC/HRMS).

[2] The certified values and uncertainties are traceable to the International System of Units (SI) through certified amino acid primary reference standards.

[3] The expanded uncertainty of the certified value includes characterization, homogeneity, stability components and is stated as the standard uncertainty of measurement multiplied by the coverage factor $k = 2$, which for a normal distribution corresponds to a coverage probability of approximately 95%. The standard uncertainty of measurement was determined in accordance with GUM "Guide to the Expression of Uncertainty in Measurement".

Sales Date

Assoc. Prof. Mustafa ÇETİNTAŞ
Acting Director

TÜBİTAK Gebze Yerleşkesi PK 54 41470 Gebze-Kocaeli /TÜRKİYE T +90 262 679 50 00 F +90 262 679 50 01 www.ume.tubitak.gov.tr

Informative Values

Parameter	Mass Concentration [1]	Uncertainty[1]	Unit
CRP	0.999	0.051	g/L

[1] The value and uncertainty have been calculated from the molality value and expanded uncertainty, using the material's density at 25 ºC (1.0047 g/cm³) and the average molecular weight (23028.2 g/mol) obtained through mass spectrometry.

Description

A unit of UME CRM 1008 contains approximately 1 mL solution of recombinant CRP (C - reactive protein) in a polypropylene vial, provided in frozen state. Detailed information regarding the content and preparation of the material is presented in the certification report.

Intended Use

This CRM is produced for use as a calibration standard for CRP measurement procedures and instruments. Additionally, it can be employed for assigning values to other calibration standards and quality control materials. The material can also be used to verify the precision and validate the accuracy of analytical methods in amino acid analysis. When utilized in immunological tests for the determination or assignment of the amount of CRP in human serum, the commutability should be confirmed.

Instructions for Use

The CRM sample to be analyzed should be removed from the freezer and allowed to equilibrate at room temperature (20 ± 3 °C) until completely thawed. After the material is dissolved completely, it should be gently mixed, followed by a brief centrifugation process (1000 g - 1 minute) to transfer the solution from the vial cap and walls to the bottle base. The dissolved material can be stored at +4 °C for up to one week. It has been tested that four freeze/thaw cycles have no effect on the molality and mass concentration.

In certification studies, **a minimum of 10 µL** of sample was used for each measurement. The minimum sample volume should be determined by the end user based on their measurement capability, taking into consideration the impact on the uncertainty of the prepared working solution for the study.

The material can be safely dispatched where the temperature does not exceed -20 °C and the transportation period of 2 weeks.

Storage Conditions

The material should be stored in an unopened vial in a dry and light-free medium at -20 °C or lower. TÜBİTAK UME cannot be held responsible for any changes that may occur in the material due to non-compliance with the reported storage conditions and usage instructions.

Safety Information

The material is a recombinant human CRP protein in aqueous solution. This material is not classified as a hazardous substance. It is suitable for *in vitro* use only and is produced exclusively for laboratory purposes. General laboratory precautions should be applied during the storage and use of the material. The use and disposal of the material are recommended to be in accordance with the existing safety regulations.

Participants

The information of the laboratory participating in the characterization study is provided in the table below.

Laboratory	Address
TÜBİTAK UME	TÜBİTAK Gebze Yerleşkesi, Barış Mahallesi, Dr. Zeki Acar Caddesi No.1, 41470 Gebze - Kocaeli / Türkiye

Methods and/or Techniques Used for the Determination of the Certified Values

In the characterization study, the monomeric molality of CRP was determined using the amino acid analysis method with Isotope Dilution Liquid Chromatography/High-Resolution Mass Spectrometry (ID-LC/HRMS). Details of the measurement method can be found in the certification report and following article:

Oztug, M., Saban, E., Asicioglu, M. *et al.* Development of UME CRM 1008: certified reference material for C-reactive protein. *Accred Qual Assur* (2024): https://doi.org/10.1007/s00769-023-01563-w

Revision History

Date	Remarks
20.02.2024	First issue.