Reference Material Institute for Clinical Chemistry Standards(ReCCS)

Certified Reference Material for Measurement of Uric Acid in Human Serum

JCCRM 811-1

Certificate of Analysis

Intended use

This certified reference material (CRM) for uric acid determination is primarily intended for use in evaluating reference methods for determining uric acid in human serum, and in validating secondary reference materials.

Instruction for use

Take out a serum vial tube of this CRM stored in a freezer, and leave it to stand vertically. Allow it to thaw naturally at room temperature for about 30 minutes. While holding the vial vertically, pinch the cap with fingers, and after confirming that the cap is screwed on firmly, or firmly tightening the cap if loose, mix the serum by gently swirling the tube approx. 20 times. Next, turn the tube upside-down slowly at least 40 times, and use the serum within the same day. Once thawed, the serum should not be frozen again for future use.

Precautions and Warnings

This CRM is a human serum material, and is intended for in-vitro diagnostic use only. This CRM has been tested for HBs antigen, HCV antibody and HIV antibody, and it was found non-reactive to these. However, since other infectious agents are not completely ruled out, handle this product as a biohazardous material capable of transmitting infectious disease, and take necessary precautions just like blood specimen in the Biosafety in Microbiological and Biomedical laboratories.

In -Vitro Use Only

Storage and Expiration period

This CRM is shipped with dry ice. After receiving it, store immediately in a freezer to keep frozen[Note)].

Note) Do not use if no dry ice remains upon arrival.

Expiration date is 1 year from the shipping date below when stored at < -70ºC ,and 3 months at ≦ -20ºC.

Shipping date

Specifications

Form: Frozen liquid

Label: JCCRM 811-1M (Medium conc.) 1 ml×2 vials

JCCRM 811-1H (High conc.) 1 ml ×2vials

JCCRM 811-1HH (Abnormally high conc.) 1 ml×2 vials

Preparation and Serum characteristics

This CRM was prepared using fresh pooled human serum (ammonium is 0.1 μg/ml). This CRM has three concentration levels and the higher levels were prepared by adding high purity creatinine, uric acid and glucose into the low level pooled serum. The materials were finally filtrated with 0.2 μm filter for sterilization and securing homogeneity. Its characterizations as well as test methods are shown below.

Density	1.024	g/cm^3	
Total protein	7.6	g/dl	Burette method
Albumin	4.5	g/dl	BCG colorimetric method
Ammonia nitrogen	0.1	mg/dl	Colorimetric method
Ascorbic acid	0.2	mg/dl	Colorimetric method
Total cholesterol	160	mg/dl	Enzymatic method

Certified values and Uncertainties

The certified values and uncertainties are as follows:

Temperature 25ºC

JCCRM 811-1M (Medium concentration)	JCCRM 811-1H (High concentration)	JCCRM 811-1HH (Abnormally high area)
4.342 ± 0.010 mg/dl	7.496 ± 0.017 mg/dl	10.715± 0.028 mg/dl
0.2583 ± 0.0006 mmol/l	0.4460 ± 0.0010 mmol/l	0.6374 ± 0.0014 mmol/l

The expanded uncertainty U was calculated from $U=ku$, where u is the combined standard uncertainty calculated according to the ISO Guide 35 (Reference 1), and k is a coverage factor. The coverage factors (95% confidence level) were k=2.2 . The standard solution was prepared with NIST SRM 913a. For the preparation of the serum samples and standard solutions to be used for the measurement of the certified values, a balance calibrated by Japan Metrology Reference System(JCSS) was used for calculating standard uncertainty of preparations (samples and standard solutions).

Measurement methods of the certified values

The certified values of this CRM were determined by Isotope Dilution Mass Spectrometry in accordance with Reference2.

Production and Measurements

This CRM was prepared at the Reference Material Institute for Clinical Chemistry Standards (ReCCS).

Analytical measurements were conducted in the Reference Material Institute for Clinical Chemistry Standards by W. Tani (Chief), K. Sakurai and I. Wada. The QC system(ISO Guide 17025 and ISO Guide 34) management was performed by M. Kawagoishi. The overall direction was done by M.Umemoto.

Certification body and Certification date

JCCRM 811-1 was certified by the certification committee of JCCLS.

Certificate issue date July 25, 2005

Katuhiko Kuwa

Chairman of the certification committee

Japanese Committee for Clinical Laboratory Standards

References

1. ISO Guide 35, Certification of Reference Materials: General and Statistical Principles, 3rd ed.; International Organization for Standardization: Geneva, Switzerland (2002).

2. Ellerbe,P.; Cohen,A.;Welch,M.J; White,V,E.; Determination of Serum Uric Acid by Isotope Dilution Mass Spectrometry as a New Candidate Definitive Method; Anal.Chem.,Val.62, 2173-2177(1990).

Provider of JCCRM 811-1

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