Reference Material Institute for Clinical Chemistry Standards (ReCCS)

Certificate of Analysis

Certified Reference Material for Measurement of Uric Acid in Human Serum

JCCRM 811-1

Intended use

This certified reference material 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 JCCRM 811-1 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

The JCCRM 811-1 is a human serum material, and is intended for in-vitro diagnostic use only. This reference material was tested for HBs antigen, HCV antibody and HIV antibody, and 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.

Storage and Expiration period

The JCCRM 811-1 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 vial tubes

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

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

Preparation and Serum characteristics

This reference material was prepared using fresh pooled human serum (ammonium is 0.1 μg/ml). It 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 expanded 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 value of this reference material was determined by Isotope Dilution Mass Spectrometry in accordance with Reference2.

~~-~~ Production and Measurements~~date~~

JCCRM 811-1 was prepared at the Reference Material Institute for Clinical Chemistry Standarads (ReCCS).

The analytical measurements were conducted in the Reference Material Institute for Clinical Chemistry Standards by W. Tani (Chief), and K. Sakurai. The QC system (ISO/IEC 17025, ISO 15195 and ISO Guide 34) management was performed by S. Takahahi. The overall direction was done by W. Tani. Our measurement procedure was verified by the comparison of our measurement results and those of the University of Ghent (Prof. L. Thienpont).~~July 29, 2004~~

- ~~Certification manager~~

Certification

~~HECTEF Standard Reference Center~~Certification date July 31, 2011

Masao Umemoto,Ph.D

Reference Material Institute for Clinical Chemistry Standards

*: ~~–~~Do not duplicate any part of this certificate without prior approval. ~~–~~When copying the entire certificate after approval, clearly indicate on the copy that it is a duplicate of the original.

References

1. ~~No. 1: ~~ISO Guide 35, Certification of Reference Materials: General and Statistical Principles, 3rd ed.; International Organization for Standardization: Geneva, Switzerland (2002).~~(1989)~~

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).~~(in Japanese)~~

~~No. 4: Sampson et al.: A Coupled-Enzyme Equilibrium Method for Measuring Urea in Serum: Optimization and Evaluation of the AACC Study Group on the Urea Candidate Reference Method, Clin Chem, 26: 816-826 (1980~~

Producer

~~(in Japanese)~~

~~(Reference material manufacturing, certification and supply)~~Reference Material Institute for Clinical Chemistry Standards (ReCCS) ~~(SR Center)~~

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~~For any technical questions regarding the present reference material, please contact the SR center.~~

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