Reference Material Institute for Clinical Chemistry Standards (ReCCS)

Certified Reference Material for Measurement of Albumin in Human Serum

JCCRM 613-3

Certificate of Analysis

SAMPLE

■ Intended use

This certified reference material (CRM) is intended primarily for use in calibrating and evaluating the accuracy of routine methods and validating working reference materials. Since neither preservatives nor additives were used, and since for preparing the reference material fresh pooled serum was used, this CRM shows consistent with specimens and is traceable to ERM-DA470k/IFCC (albumin).

*Total Protein is not shown on this certificate for JCCRM 613-3 because it is under discussion about what to use for calibration.

■ Certified values and uncertainties.

Table 1. Albumin Certified Values

Unit: g/dL (25℃)

Level	Certified value	Uncertainty
JCCRM 613-3 M	**4.35**	**0.24**
JCCRM 613-3 L	**3.19**	**0.18**

Uncertainty is expressed as expanded uncertainty, U, calculated as $U = ku$, where u is the combined standard uncertainty calculated according to the ISO Guide [1], and k is a coverage factor. The coverage factors (95 % level of confidence) $k = 2$ is used for the calibration.

■ Traceability

The albumin concentrations were assayed by the JSCC reference method: ion-exchange HPLC post-column colorimetric method using BCG regent[2] calibrated by ERM DA470k/IFCC(certified value: 3.72 ± 0.12 g/dL).

■ Instructions for use

(1) Take out a serum vial tube of this CRM and thaw the frozen serum by allowing the tube to stand with the cap-side up at room temperature for approximately 30 minutes.

(2) While holding the serum tube vertically with the cap-side up, hold the cap with fingers, and confirm that the cap is tightly screwed on. If the cap is loose, tighten it securely. Then mix the serum by gently swirling the tube approximately 40 times. Next, turn the tube upside-down slowly at least 40 times to secure homogeneity.
Do not shake vigorously.
Note: Insufficient mixing leads to incorrect measurement results.

(3) Conduct sampling of the mixed serum for measurements. Unless used immediately, tighten the vial cap and refrigerate it for use in the same day.
Note: Once thawed, the serum should not be frozen again for future use.

■ Precautions and Warnings

This CRM is prepared from human serum material and is intended for **in-vitro diagnostic use only.** This CRM has been tested for HBs antigens, HCV antibodies and HIV antibodies, and it is 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 diseases, and take necessary precautions just as like working with any biological samples at Biosafety Level 2 in microbiological and biomedical laboratories.

■ Storage and Expiration

This CRM reference material is distributed or shipped in frozen condition. After receiving, store it immediately in a deep freezer (below -70 ℃). Do not use the material if no dry ice remains upon arrival.

The shelf life of this material is 12 months from the shipping date when stored at – 70 ℃ or below at an end user.

■ Specifications

This CRM consists of 4 plastic vial tubes; 2 tubes for each of two different concentration levels (Level 1: low, Level 2: midium). Each tube contains 0.5 ml of human serum.

・Level 1: low	JCCRM 613-3L
・Level 2: medium	JCCRM 613-3M

■ Preparation

This CRM was prepared by pooled frozen different human serum according to CLSI (Clinical and Laboratory Standard Institute) C37-A[3] . JCCRM 613-3 L was prepared by conducting JCCRM 613-3 M.

■ Certification and Certification date

The production of this CRM was performed according to ISO Guide 34 at the production center of ReCCS.

Date of Certification
May 11 , 2022
Provider of JCCRM 613-3

■ References

1) Evaluation of measurement data - Guide to the expression of uncertainty in measurement. ISO/IEC Guide 98-3 (JCGM 100:2008).
2) Rinsyokagaku 42 : 68-79 (2013).
3) CLSI Publication C37-A. Preparation and validation of commutable frozen human serum pools as secondary reference materials for cholesterol measurement procedures; approved guideline: CLSI, Wayne, PA, 1999.
4) Japan Association for Clinical Laboratory Science VOL. 39(5): 621-629 (2014)

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