

Reference Material Institute for Clinical Chemistry Standards (ReCCS)

**Certified Reference Material for Measurement of
Inorganic Phosphorus in Human Serum**

JCCRM 324-6

Certificate of Analysis

■ **Intended use**

This CRM is intended primarily for use in evaluating the accuracy of clinical procedures for the determination of inorganic phosphorus(IP) in human serum.

■ **Certified concentration values and uncertainties**

Metrological traceability is to the SI derived unit for mass concentration (expressed as milligram per deciliter).

Table 1. Certified Concentration Values for IP

Unit: mg/dL

Item	Certified value	Uncertainty
JCCRM 324-6L	3.74	0.07
JCCRM 324-6M	6.71	0.12
JCCRM 324-6H	9.67	0.18

The expanded uncertainty U (95 % level of confidence) shown for each certified value in the above table is obtained from the equation $U=ku$, where u is the combined standard uncertainty calculated according to the ISO Guide 36¹⁾, and k is a coverage factor. The coverage factor k , determined from the Student's t distribution, is $k=2.0$.

■ **Measurement method for certified values**

The certified values were determined by Ion chromatography²⁾ by the ReCCS.

■ **Traceability**

Traceability for IP measurement to SI units was assured via calibration against NIST SRM 200b (Certified mass fractions of Phosphorus is 22.769 % \pm 0.010 %). Standard solutions and sample solutions used in the measurements were prepared by a gravimetric method using a calibrated balance.

■ **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. Next, turn the tube upside-down slowly at least 40 times to secure homogeneity.
- (3) Conduct sampling of the mixed serum for measurements. Use it within 3 hours. 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 for use: In vitro use only**

This CRM is prepared from human serum and shown to be negative to the HBs antigens, HCV antibodies and HIV antibodies. However, since other infectious agents are not completely ruled out, handle this CRM as a biohazardous material capable of transmitting infectious diseases.

■ Preparation and Serum property

This CRM was prepared from pooled human serum and prepared low levels at first. Next the middle level and high level are prepared by adding NIST SRM 200b to the low levels.

■ Storage and expiration

This CRM is must be stored in a deep freezer (below $-70\text{ }^{\circ}\text{C}$) upon receipt.

Under this condition, its shelf life is 12 months from the shipping date (see the label of the outer case).

The shelf life for storage at $-20\text{ }^{\circ}\text{C}$ is one month.

■ Product specifications

A single set of this CRM consists of 6 vials, each vial contains 1 mL of human serum. There are 2 vials for each of three different concentration levels indicated below.

- Low Level JCCRM 324-6 L
- Middle Level JCCRM 324-6 M
- High Level JCCRM 324-6 H

■ Characteristics of this CRM

The characteristics of this CRM are as follows.

Item	JCCRM 324-6	unit	Method
Total protein	7.1	g/dL	Biuret method
Albumin	4.1	g/dL	BCG colorimetric method
Ammonia nitrogen	0.2	mmol/L	Colorimetric method
Total cholesterol	169	mg/dL	Enzymatic method
Triglycerides	80	mg/dL	Enzymatic method
Calcium	9.1	mg/dL	MXB method

■ References

- 1) Evaluation of measurement data - Guide to the expression of uncertainty in measurement, ISO/IEC Guide 98-3 (JCGM 100:2008).
- 2) RinsyoKagaku volume 24, 2 , 87b-90b, 1995

Date of certification

July , 15, 2021

Provider of JCCRM 324-6

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