

Standard Reference Material® 967b

Creatinine in Frozen Human Serum

CERTIFICATE OF ANALYSIS

Purpose: The certified values delivered by this Standard Reference Material (SRM) are intended for validating methods for determining creatinine in human serum and plasma and qualifying control materials produced in-house and analyzed using those methods.

Description: A unit of SRM 967b consists of two vials each of two materials: low level and high level. Each bottle contains approximately 1.0 mL of serum.

Certified Values: These values are traceable to International System of Units (SI). The values are reported on an as-received basis [1,2].

Table 1. Certified Values for Creatinine in SRM 967b

Material	Mass Fraction ^(a) (μg/g)	Mass Concentration ^(a,b) (mg/dL)	Amount Concentration ^(a,c) (mmol/L)
Low Level	6.825 ± 0.144	0.697 ± 0.015	0.0616 ± 0.0013
High Level	38.35 ± 0.88	3.926 ± 0.090	0.3471 ± 0.0080

^(a) Values are expressed as $x \pm U_{95\%}(x)$, where x is the certified value and $U_{95\%}(x)$ is the expanded uncertainty of the certified value. The true value of the analyte is believed to lie within the interval $x \pm U_{95\%}(x)$ with 95 % confidence. To propagate this uncertainty, treat the certified value as a normally distributed random variable with mean x and standard deviation $U_{95\%}(x)/2$.

^(b) Mass concentration levels were calculated from mass fractions using measured serum density listed in Table 2.

^(c) Amount concentration values, mmol/L, are calculated from the mass concentration results, milligram per deciliter, via multiplication by 10/M, where M is the molar mass, grams per mol, of creatinine. The molar mass used is: 113.1182 g/mol. This molar mass has associated standard uncertainty $u(M) = 0.0025$ g/mol.

Table 2. Certified Serum Density of SRM 967b at 23 °C

Measurand	Value ^(a) (g/mL)
Low Level Serum Density	1.0214 ± 0.0020
High Level Serum Density	1.0238 ± 0.0009

^(a) Value is expressed as $x \pm U_{95\%}(x)$, where x is the certified value and $U_{95\%}(x)$ is the expanded uncertainty of the certified value. The true value of the analyte is believed to lie within the interval $x \pm U_{95\%}(x)$ with 95 % confidence. To propagate this uncertainty, treat the certified value as a normally distributed random variable with mean x and standard deviation $U_{95\%}(x)/2$.

Period of Validity: The certified values delivered by **SRM 967b** are valid within the measurement uncertainty specified until **31 August 2030**. The certified values are nullified if the material is stored or used improperly, damaged, contaminated, or otherwise modified.

Maintenance of Certified Values: NIST will monitor this SRM over the period of its validity. If substantive technical changes occur that affect the certification, NIST will issue an amended certificate through the NIST SRM website (<https://www.nist.gov/srm>) and notify registered users. SRM users can register online from a link available on the NIST SRM website or fill out the user registration form that is supplied with the SRM. Registration will facilitate notification. Before making use of any of the values delivered by this material, users should verify they have the most recent version of this documentation, available through the NIST SRM website (<https://www.nist.gov/srm>).

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Safety: SRM 967b IS INTENDED FOR RESEARCH USE. This is a human-source material. Handle product as a Biosafety Level 2 material and should be handled according to applicable federal, state, and/or local regulations and according to policies and procedures of recipient's organization. The supplier has reported that each donor unit of serum used in the preparation of this product was tested by FDA-licensed tests and found to be non-reactive for human immunodeficiency virus (HIV), HIV-1 and HIV-2, hepatitis B surface antigen, and hepatitis C.

Source: This SRM was developed after an appropriate human subjects research determination by NIST.

Storage: The serum is shipped frozen (on dry ice) and, upon receipt, should be stored at -80°C until ready for use. The SRM should not be exposed to sunlight or ultraviolet radiation. Storage of thawed material at room or refrigerator temperatures may result in changes in creatinine concentrations.

Use: Vials of the SRM to be analyzed should be removed from the freezer and allowed to stand at room temperature (20°C to 25°C) until thawed. After the material is thawed, it should be used immediately. The material should be swirled gently to mix it before aliquots are withdrawn.

Additional Information: Full details on the production, analysis, and statistical evaluation of SRM 967b are provided in NIST Special Publication 260-239.

REFERENCES

- [1] Beauchamp, C.R.; Camara, J.E.; Carney, J.; Choquette, S.J.; Cole, K.D.; DeRose, P.C.; Duewer, D.L.; Epstein, M.S.; Kline, M.C.; Lippa, K.A.; Lucon, E.; Molloy, J.; Nelson, M.A.; Phinney, K.W.; Polakoski, M.; Possolo, A.; Sander, L.C.; Schiel, J.E.; Sharpless, K.E.; Toman, B.; Winchester, M.R.; Windover, D.; *Metrological Tools for the Reference Materials and Reference Instruments of the NIST Material Measurement Laboratory*; NIST Special Publication 260-136, 2021 edition; National Institute of Standards and Technology, Gaithersburg, MD (2021); available at <https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.260-136-2021.pdf> (accessed Sep 2023).
- [2] Camara, J.; Wood, E.S.C.; Toman, B.; *Certification of Standard Reference Material[®] 967b Creatinine in Frozen Human Serum*; NIST Special Publication 260-239; National Institute of Standards and Technology, Gaithersburg, MD (2023); available at <https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.260-239.pdf> (accessed Sep 2023).

If you use this SRM in published work, please reference:

Camara J, Wood ESC, Toman B (2023) Certification of Standard Reference Material[®] 967b Creatinine in Frozen Human Serum. (National Institute of Standards and Technology, Gaithersburg, MD), NIST Special Publication (SP) 260-239. <https://doi.org/10.6028/NIST.SP.260-239>

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