NIST NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY
U.S. DEPARTMENT OF COMMERCE

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Standard Reference Material® 2921a
Human Cardiac Troponin Complex
CERTIFICATE OF ANALYSIS

Purpose: The certified value delivered by this Standard Reference Material (SRM) is intended to validate methods for determining human cardiac troponin I (cTnI) concentrations in human clinical samples.

Description: A unit of SRM 2921a consists of three vials. Each vial contains approximately 115 µL of a frozen aqueous solution containing the human cardiac troponin complex.

Certified Value: The certified value and uncertainty for the mass concentration of cTnI in SRM 2921a are listed in the table below. A certified value is a value for which NIST has the highest confidence in its accuracy in that all known or suspected sources of bias have been investigated or accounted for [1]. The certified mass concentration value is metrologically traceable to the International System of Units (SI) unit of mass concentration expressed as milligrams per liter [1,2] through the use of NIST SRM 2921 to calibrate the certification measurements of SRM 2921a.

Certified Mass Concentration Value for Human Cardiac Troponin I in SRM 2921a

Measurand	Concentration[(a)] (mg/L)
Human Cardiac Troponin I (cTnI)	139.6 ± 7.4

[(a)] Values are expressed as $x \pm U_{95\%}(x)$, where x is the certified value, $U_{95\%}(x)$ is the expanded uncertainty of the certified value, and the coverage factor is $k = 1.98$ [3–4].

Additional Information: Methods used to analyze SRM 2921a and information about preparation are provided in Appendix A.

Period of Validity: The certified value delivered by **SRM 2921a** is valid within the measurement uncertainty specified until **16 March 2036**. The certified value is nullified if the material is stored, misused, damaged, contaminated, or otherwise modified.

Maintenance of Certified Value: NIST will monitor this SRM over the period of its validity. If substantive technical changes affect the certification, NIST will issue an amended certificate through the NIST SRM website (https://www.nist.gov/srm). Before using the value 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 2921a IS INTENDED FOR RESEARCH USE. This is a human-source material. SRM 2921a is 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 the recipient's organization. The supplier of this human protein has reported that the donor tissue, from which this protein was extracted, has been tested and found non-reactive for Hepatitis B surface antigen (HbsAg), human immunodeficiency virus (HIV), and human immunodeficiency virus antigen (HIV-1Ag).

Storage: SRM 2921a is shipped frozen (on dry ice) and, upon receipt, should be stored frozen until used. A temperature of –20 °C is acceptable for storage up to one week. If a longer storage time is anticipated, the material should be stored at –80 °C or at temperatures consistent with the range (typically –70 °C to –86 °C) provided by commercial –80 °C freezers. The SRM should not be exposed to sunlight or ultraviolet radiation. Storage of thawed material at room (20 °C to 25 °C) or refrigerator (5 °C to 8 °C) temperatures may result in degradation or modification of the constituent proteins.

Use: Prior to use, the vial (or vials) should be allowed to thaw at room temperature (20 °C to 25 °C) until completely thawed. The contents of the vials should then be gently mixed before removing a test portion for analysis. The certificate only applies to the initial use, and the same results are not guaranteed if the remaining material is used later.

Full details on the production and evaluation of SRM 2921a are provided free of charge in reference 2**.**

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 Mar 2026).

[2] Bunk, D.M.; Newton, D.; *Certification of Standard Reference Material® 2921a Human Cardiac Troponin Complex*; NIST Special Publication 260-263; National Institute of Standards and Technology, Gaithersburg, MD (2026); available at https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.260-263.pdf (accessed Mar 2026).

[3] JCGM 100:2008; *Evaluation of Measurement Data — Guide to the Expression of Uncertainty in Measurement (ISO GUM 1995 with Minor Corrections)*; Joint Committee for Guides in Metrology (2008); available at https://www.bipm.org/en/committees/jc/jcgm/publications (accessed Mar 2026); see also Taylor, B.N.; Kuyatt, C.E.; *Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results*; NIST Technical Note 1297; National Institute of Standards and Technology, Gaithersburg, MD (1994); available at https://www.nist.gov/pml/nist-technical-note-1297 (accessed Mar 2026).

[4] JCGM 101:2008 *Evaluation of Measurement Data—Supplement 1 to the "Guide to the Expression of Uncertainty in Measurement"—Propagation of Distributions Using a Monte Carlo Method*; Joint Committee for Guides in Metrology (2008); available at https://www.bipm.org/en/committees/jc/jcgm/publications (accessed Mar 2026)

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

Bunk, D.M.; Newton, D.; *Certification of Standard Reference Material® 2921a Human Cardiac Troponin Complex*; NIST Special Publication 260-263; National Institute of Standards and Technology, Gaithersburg, MD (2026); available at https://doi.org/10.6028/NIST.SP.260-263 (accessed Mar 2026).

Certain commercial equipment, instruments, or materials may be identified in this Certificate of Analysis to specify the experimental procedure adequately. Such identification does not imply recommendation or endorsement by the National Institute of Standards and Technology, nor does it indicate that the materials or equipment identified are necessarily the best available for the purpose.

Users of this SRM should ensure that the Certificate of Analysis in their possession is current. This can be accomplished by contacting the Office of Reference Materials 100 Bureau Drive, Stop 2300, Gaithersburg, MD 20899-2300; telephone (301) 975-2200; e-mail srminfo@nist.gov; or the Internet at https://www.nist.gov/srm.

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APPENDIX A

Sources and Preparation. The human cardiac troponin complex used to prepare SRM 2921a was procured from Fitzgerald Industries International (now Biosynth Ltd.). The stock solution for SRM 2921a was prepared by diluting the concentrated solution of the human troponin complex obtained from Fitzgerald Industries International with an aqueous buffer containing approximately 20 mmol/L tris(hydroxymethyl)aminomethane, 150 mmol/L sodium chloride, and 5 mmol/L calcium chloride with a pH of approximately 7.5. The bulk human cardiac troponin complex solution was aliquoted into sterile 0.5 mL polypropylene screw-capped vials with a fill volume of approximately 115 µL.

Analysis. The determination of the mass concentration of human cardiac troponin I in SRM 2921a was performed at NIST. A liquid chromatography-mass spectrometry (LC-MS) method was developed to measure several molecular ion signals from the intact cTnI molecule through electrospray ionization after reversed-phase chromatography. The LC-MS method was calibrated using calibrators prepared from NIST SRM 2921. A detailed description of this methodology can be found in reference 2, which also contains results from the qualitative analysis of the protein structures of the human cardiac troponin complex in SRM 2921a.

Homogeneity Analysis: Homogeneity was assessed during the certification analysis. A stratified sampling plan was devised to test for homogeneity across the fill lot of vials. The data showed no apparent trend when the measured concentration was plotted against the sequence in which the vials were filled.

Stability: The stability of the mass concentration of cTnI in SRM 2921a is assumed to be similar to that of SRM 2921 as both materials are highly comparable in protein structure and composition. There have been no indications of instability for SRM 2921 since it was first issued in 2004. As such, SRM 2921a is expected to be highly stable when stored properly.

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