U.S. Department of Commerce
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Secretary

National Bureau of Standards
Ernest Ambler, Director

National Bureau of Standards

Certificate of Analysis

Standard Reference Material 1951

Cholesterol in Human Serum (Frozen)

(In Cooperation with the Centers for Disease Control)

This Standard Reference Material (SRM) is intended primarily for use in evaluating the accuracy of clinical procedures for the determination of cholesterol in serum, in calibrating instruments and equipment used in these procedures, and in validating working or secondary reference materials. It is also intended for use in evaluating the reliability of clinical procedures for triglycerides, which were determined in this SRM by a chromotropic acid method at the Centers for Disease Control (CDC). SRM 1951 consists of six bottles of frozen serum, two each of three different concentration levels of cholesterol. Each bottle contains approximately 1.3 mL of serum. The serum was donated by CDC.

WARNING: FOR IN VITRO DIAGNOSTIC USE ONLY

HANDLE AS IF CAPABLE OF TRANSMITTING DISEASE!

FOLLOW STORAGE INSRUCTIONS

CERTIFIED CHOLESTEROL CONCENTRATIONS: Cholesterol was determined at NBS by a modification [1] of the isotope dilution mass spectrometric definitive method [2]. The certified concentrations are listed in Table 1.

Table 1. Certified Cholesterol Concentrations and Uncertainties

Concentration Level	Concentration and Uncertainty, mmol/L	Concentration and Uncertainty, mg/dL	Number of Vials
Low (1951-1)	5.440 ± 0.064	210.36 ± 2.46	9
Medium (1951-2)	6.266 ± 0.040	242.29 ± 1.53	9
High (1951-3)	7.292 ± 0.047	281.97 ± 1.82	9

Notes
1. The certified concentrations apply to thawed serum at room temperature (20 to 25 °C).
2. The uncertainties are expressed as tolerance intervals to cover the true concentration in 95% of the vials of SRM 1951 with 95% probability.
3. Number of vials analyzed are as indicated. One sample from each vial was measured twice according to the protocol in Ref. 1.

Cholesterol was determined by L.T. Sniegoski, NBS Organic Analytical Research Division, and P.M. Ellerbe, NBS Research Associate, College of American Pathologists.

The statistical analysis of the data was performed by S.B. Schiller and K.R. Eberhardt of the NBS Statistical Engineering Division. The overall direction and technical measurements leading to the certification were under the chairmanship of M.J. Welch, E. White V, and R. Schaffer, NBS Organic Analytical Research Division.

Gaithersburg, MD 20899
February 29, 1988

Stanley D. Rasberry, Chief
Office of Standard Reference Materials

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Technical and support aspects involved in preparation, certification, and issuance of this Standard Reference Material were coordinated through the Office of Standard Reference Materials by R. Alvarez.

INSTRUCTIONS FOR USE

Thaw and allow to come to room temperature (20 to 25 ° C) and swirl to mix.

STORAGE: The frozen serum should be stored at a temperature of approximately -20 °C or lower. It should not be exposed to sunlight or ultraviolet radiation. Under the recommended storage conditions, this SRM is expected to be stable for at least two years. Should evidence indicate degradation, purchasers will be notified by NBS. The material is not certified for use after two years from date of shipment.

INFECTIOUS DISEASE TESTING

The supplier of this serum has tested the source materials used to prepare this product and found them to be negative for Hepatitis B Surface Antigen (HB_sAg) and for antibody to human immunodeficiency virus (HIV). However, because no test method can offer complete assurance that HIV, hepatitis B virus, or other infectious agents are absent, these specimens should be handled at the Biosafety Level 2 as recommended for any potentially infectious human serum or blood specimen in the Centers for Disease Control/National Institutes of Health manual "Biosafety in Microbiological and Biomedical Laboratories," 1984, 11-13.

ADDITIONAL CHARACTERIZATION OF SRM 1951
BY THE CENTERS FOR DISEASE CONTROL, ATLANTA, GA

Cholesterol Concentrations by the Reference Method: Cholesterol was determined by Charlene Griffin using the modified Abell-Kendall Method [3,4] developed by CDC. The results, as reported by CDC, are listed in Table 2.

Table 2. CDC Reference Method Values for Cholesterol

Concentration Level	Mean Cholesterol Concentration, mg/dL	Standard Deviation	Number of Determinations	CV (%)
Low (1951-1)	214.12	1.08	48	0.51
Medium (1951-2)	245.83	1.74	48	0.70
High (1951-3)	286.38	1.35	48	0.71

Triglyceride Concentration by the CDC Chromotropic Acid Method: Triglycerides were determined by William Slayton (retired), CDC Lipid Reference Section, Clinical Chemistry Division. The general method has been described [5,6,7,8]. The results, as reported by CDC, are listed in Table 3.

Table 3. CDC Triglyceride Concentrations and Uncertainties

Concentration Level	Mean Triglyceride Concentration, mmol/L	Standard Deviation	Number of Determinations	CV (%)
Low (1951-1)	1.35	0.04	47	2.82
Medium (1951-2)	1.92	0.06	45	2.94
High (1951-3)	2.39	0.03	47	1.32

REFERENCES:

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3. Duncan, I.W., Mather, A., and Cooper, G.R. The procedure for the proposed cholesterol reference method. Clinical Chemistry Division, Center for Environmental Health, US Dept. of Health and Human Services, Public Health Service, Atlanta, GA, Centers for Disease Control, (1982).

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5. Carlson, L.A. and Wadstrom, L.B. Determination of glycerides in blood serum, Clinica Chimica Acta, 4, 197-205, (1959).

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7. Lofland, H.B., Jr., A semiautomated procedure for the determination of triglycerides in serum, Analytical Biochemistry, 9, 393-400, (1964).

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