



UNITED STATES DEPARTMENT OF COMMERCE
National Institute of Standards and Technology
Gaithersburg, Maryland 20899-0001

DATE: 07 August 2014

Product Identifier

SRM Number: 1599

SRM Name: Anticonvulsant Drug Level Assay Standard

Under the U.S. Department of Labor, Occupational Safety and Health Administration (OSHA) 29 CFR 1910.1200, this Standard Reference Material (SRM) is NOT classified as a physical hazard or a health hazard, a simple asphyxiant, combustible dust, pyrophoric gas, or hazard not otherwise classified. There are no hazard pictograms, hazard statements or signal word associated with it. Safety Data Sheet information is not required. This document may be used in conjunction with your hazard communication program.

Exemption: 1910.1200 (b) (6) (xii). This SRM is a biological material and should be considered a potential biological hazard.

Description: This SRM is certified for the concentrations of two anticonvulsant drugs (valproic acid and carbamazepine) in a processed human serum base. It is intended for use in the calibration and standardization of procedures employed in clinical laboratories for the determination of these drugs in serum. It can also be used for the critical evaluation of working or secondary reference solutions prepared either in-house or by a commercial supplier. This SRM is supplied as a set of four different freeze-dried preparations (three different concentrations and a blank).

Additional Notes for Biomaterials: SRM 1599 IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY. THIS IS A HUMAN SOURCE MATERIAL. HANDLE PRODUCT AS A BIOHAZARDOUS MATERIAL CAPABLE OF TRANSMITTING INFECTIOUS DISEASE. The supplier of this serum has reported that this product has been tested by an FDA-approved method and found non-reactive/negative hepatitis B antigen. However, no known test method can offer complete assurance that hepatitis B virus, or other infectious agents are absent from this material. Accordingly, this human blood-based product should be handled at the Biosafety Level 2 or higher as recommended for any potentially infectious human serum or blood specimen by the Centers for Disease Control and Prevention (CDC) Office of Safety, Health, and Environment and the National Institutes of Health (NIH). See Certificate of Analysis for storage and use instructions.

Disposal: SRM 1599 components and derived solutions should be disposed of in accordance with local, state, and federal regulations.

Transport Information: This material is not regulated by the U.S. Department of Transportation (DOT) and/or International Air Transportation Association (IATA).

Disclaimer: This document was prepared carefully, using current references. Users of this SRM should ensure that this document and the corresponding Certificate of Analysis in their possession are current. This can be accomplished by contacting the SRM Program: telephone (301) 975-2200; fax (301) 948-3730; e-mail srmmsds@nist.gov; or via the Internet at <http://www.nist.gov/srm>.