CERTIFICATE OF ANALYSIS

Reference Standard - ChE

JCCLS CRM – 002d

Mean catalytic concentrations[1)] in reconstituted material as determined by the JSCC primary reference procedures at 37 ℃	Certified values[2)] U/L	Uncertainties[3) 4)] U/L
Cholinesterase	539	± 9

1) The catalytic concentrations were determined by the JSCC primary reference measurement procedures at 37℃.
2) The certification procedure was based on ISO GUIDE 35. The certified values were unweighted mean of 23 unweighted mean values independently obtained by 23 labs. These certified values are valid until 11/2013; this validity may be extended as further evidence of stability is available.
3) Each estimated expanded uncertainty U was calculated as U= ku, where k was the coverage factor corresponding to the 95% level of confidence and u was the combined standard uncertainty, as defined in the Guide to Expression of Uncertainty in Measurement (GUM), 1995. Each uncertainty includes homogeneity and experimental error components.
4) The inter-laboratory and vial-to-vial differences, as factors causing variation of experimental data, were evaluated by three-way analysis of variance.

INTENDED USE

This material is equivalent to the secondary calibration material in metrological traceability defined in ISO 18153.

The material is intended to provide, when reconstituted, a calibration solution with each known catalytic concentration of Cholinesterase assayed by the JSCC reference method (1, 2). This material can also be used for evaluation of routine methods in accordance with the JSCC reference methods (1, 2).

DESCRIPTION OF MATERIAL

This human multi-enzyme reference material (human multi-ERM) was lyophilized from a solution. The origin of the enzyme was pseudo-ChE obtained from human plasma, The matrix was human pooled serum.

VIAL CONTENTS AND PACKAGE

1 set : 1 bottle (3ml: reconstituted) x 2 . The bottle is a glass one which is tightly sealed.

The package accommodating a bottle is designed for avoiding shock, which is wrapped with cushion in order to avoid damage.

TRANSPORTATION AND STORAGE

This material should be transported and stored frozen (at lower than -20℃).

RECONSTITUTION PROCEDURE AND USAGE

1. The entire contents of each vial should be completely dissolved in an accurately measured amount of water according to the procedure below:

(1) Allow the vial to equilibrate at room temperature.
(2) Tap the vertically positioned vial gently to ensure that the lyophilized material is at the bottom of the vial.
(3) Carefully remove the stopper.
(4) Reconstitute by slow addition to the sides of the vial of (3.00 ± 0.015) mL distilled water (15-25 °C) with calibrated volumetric equipment. Note the temperature.
(5) Replace the stopper.
(6) Let to stand for 10 minutes at room temperature.
(7) Mix gently by reversing 20-30 times in order to dissolve perfectly.

2. Keep the reconstituted material at 2 to 8°C.
3. Each enzyme activity must be measured within 24 hours from the reconstitution time and the vial should not be stored for re-use.
   The minimum amount of sample to be used is 50 μ l.
4. After reconstitution according to the above instruction, the material is regarded as a homogeneous solution.

EXPIRATION DATE

This material should be kept at lower than –20 °C. The certified value is valid until the end of December 2023.

* This material will be monitored periodically over the period until the expiration date. If there are substantive changes with regard to its stability, it will be notified to the purchaser, and distribution will be stopped.

EVALUATION

The commutability of this material was evaluated by Certification Committee, Japanese Committee for Clinical Laboratory Standards (JCCLS), Tokyo (JAPAN).

ATTENTION

1. Before using this material, thoroughly read the present inserted document.
2. Do not refreeze the material for re-use once it has been dissolved.

WARNINGS

1. This material has been tested to be free of HBs antigen, HIV antibody (HIV-1 and HIV-2), HTLV-1 antibody and HCV antibody. Regarding other infectious viruses, as no test method that can ensure non-infectivity has yet been established, this material must be handled like any other routine test sample with the assumption it poses a risk for infection.
2. If this material comes in contact with the eyes or mouth, thoroughly wash the affected area using water, and consult a medical doctor.
3. Used containers are disposed of as medical or industrial waste in accordance with the waste material regulations.

In vitro use only

MANUFACTURER

This material was manufactured by Asahi Kasei Pharma Corporation.

DATE OF CERTIFICATION AND CERTIFICATION BODY

December , 2023

Shigemi Hosogaya,　Yasushi Takagi

The Japanese Committee for Clinical Laboratory Standards

http://tc.xii.jp/jccls/

PROVIDER

ReCCS (Reference Material Institute for Clinical Chemistry Standards)

1-3-3 Azaminominami, Aoba-ku, Yokohama, 225-0012 , Japan

TEL　81-45-507-6145

FAX　81-45-530-9036

URL　http://www.reccs.or.jp

FOR INQUIRY

ReCCS (Reference Material Institute for Clinical Chemistry Standards)

1-3-3 Azaminominami, Aoba-ku, Yokohama, 225-0012 , Japan

TEL　81-45-507-6145

FAX　81-45-530-9036

e-mail　ando@reccs.net