FUJIFILM Wako Pure Chemical Corporation Mie Plant

2613-2, Oaza Ogohara, Komono-cho, Mie-gun, Mie Pref 510-1222 Japan

meets the following criteria. On the basis of this, Japan Accreditation Board (JAB) grants accreditation to the said reference material producer.

Applicable accreditation criteria : JIS Q 17034:2018 (ISO 17034:2016)
Scope of accreditation : As described in the appendix.
Premises covered by accreditation : As described in the appendix.
Expiry date of accreditation : September 30, 2023

Y. Tizuka, President
Japan Accreditation Board

Renewed (2) September 2, 2019
Initial accreditation September 30, 2011

Issue No. : RMP00010-20190902
FUJIFILM Wako Pure Chemical Corporation Mie Plant

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Scope of Accreditation
- Biological and clinical properties
  - B2 Clinical chemistry
  - B2.3 Enzymes

- Type of reference Material : Certified Reference Material
- Name of reference material : Enzyme Calibrator
  (AST, ALT, ALP, CK, LD, γ-GT, AMY, ChE)

- Test method : Manufacturer’s standing measurement procedure (No.41-5719)

- Range of property values
  - AST : 130〜180 U/L
  - ALT : 130〜180 U/L
  - ALP : 380〜520 U/L
  - CK : 380〜520 U/L
  - LD : 340〜460 U/L
  - γ-GT : 120〜170 U/L
  - AMY : 250〜350 U/L
  - ChE : 320〜660 U/L

- The expanded uncertainties of property values (k=2)
  - AST : 3%
  - ALT : 3%
  - ALP : 4%
  - CK : 3%
  - LD : 3%
  - γ-GT : 4%
  - AMY : 3%
  - ChE : 3%

An expanded uncertainty represents Calibration and Measurement Capability (CMC) at approximately 95% level of confidence, including homogeneity and stability of the material.

Japan Accreditation Board

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