

Reference Material Producer

Accreditation Certificate

Accreditation No.RMP00010

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

Scope of accreditation

Premises covered by accreditation

Expiry date of accreditation

: JIS Q 17034:2018 (ISO 17034:2016)

: As described in the appendix.

: As described in the appendix.

: September 30, 2023

Renewed (2)
Initial accreditation

September 2, 2019 September 30, 2011

Y. Iizuka, President

Japan Accreditation Board

Issue No.: RMP00010-20190902



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FUJIFILM Wako Pure Chemical Corporation Mie Plant 2613-2, Oaza Ogohara, Komono-cho, Mie-gun, Mie Pref 510-1222 Japan Scope of Accreditation

B Biological and clinical properties B2 Clinical chemistry B2.3 Enzymes

• Type of reference Material : Certified Reference Material

Name of reference material : Enzyme Calibrator

 $(AST,ALT,ALP,CK,LD,\gamma-GT,AMY,ChE)$

• 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% \gamma-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.

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