



JAB

Reference Material Producer

Accreditation Certificate

Accreditation No. RMP00020

NPO Japanese Committee for Clinical Laboratory Standards

***48 Kanda Higashimatsushita-cho Chiyoda-ku Tokyo
101-0042, 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 0034:2012 (ISO Guide 34:2009)
Scope of accreditation	: As described in the appendix.
Premises covered by accreditation	: As described in the appendix.
Expiry date of accreditation	: March 31, 2021

Renewed (1)	March 24, 2017
Initial accreditation	March 29, 2013

K. Chiba, Chairman
Reference Material Producer Accreditation Committee

Y. Mizuka, President
Japan Accreditation Board



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NPO Japanese Committee for Clinical Laboratory Standards

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48 Kanda Higashimatsushita-cho Chiyoda-ku Tokyo 101-0042, 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 : JSCC Enzyme
- Test method : JSCC consensus method and
JCCLS standard method for enzyme activity measurement
- Range of property values, the expanded uncertainties of property values($k=2$)

Aspartate transaminase (AST):	100U/L-200U/L	2.4%
Alanine transaminase (ALT):	100U/L-200U/L	2.4%
Creatine Kinase (CK):	300U/L-600U/L	2.2%
Alkaline Phosphatase (ALP) :	300U/L-600U/L	3.0%
Lactate dehydrogenase (LD) :	300U/L-600U/L	1.9%
γ -glutamyltransferase (γ -GT):	100U/L-200U/L	3.2%
amylase:	250U/L-550U/L	2.5%

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

B Biological and clinical properties

B2 Clinical chemistry

B2.1 Proteins

- Type of reference material : Non-certified reference material,
Unfit for metrological traceability
- Name of reference material : Multianalyte Conventional Reference Material : MacRM-001
- Test method for each property:
C-reactive protein (CRP) : Latex turbidimetric assay
Albumin : modified BCP assay
IgG : Immunoturbidimetric assay, nephelometric immunoassay
IgA : immunoturbidimetric assay, nephelometric immunoassay
IgM : immunoturbidimetric assay, nephelometric immunoassay
Total protein : Biuret test
- Range of property values, Origin CRM, the expanded uncertainties of property values($k=2$)

C-reactive protein (CRP) (mg/dL) :	3.0-5.0	IRMM ERM-DA474	6.6%
Albumin (g/dL) :	4.0-5.0	IRMM ERM-DA470k	3.6%
IgG (mg/dL) :	800-1600	IRMM ERM-DA470k	2.5%
IgA (mg/dL) :	200-500	IRMM ERM-DA470k	3.2%
IgM (mg/dL) :	50-200	IRMM ERM-DA470k	4.3%
Total protein (mg/dL) :	6.5-8.5	NIST SRM927	2.2%

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B Biological and clinical properties

B2 Clinical chemistry

B2.2 Lipids and Lipoproteins

- Type of reference material : Non-certified reference material,
Unfit for metrological traceability
- Name of reference material : Multianalyte Conventional Reference Material : MacRM-001
- Test method for each property:
Total cholesterol: Cholesterol oxidase method, Cholesterol dehydrogenase method
Triglyceride: Enzyme colorimetric method (elimination of free glycerol)
HDL-cholesterol: Direct method
LDL- cholesterol: Direct method
- Range of property values, Origin CRM, the expanded uncertainties of property values($k=2$)

Total cholesterol (mg/dL) :	150—250	NIST SRM1951c	1.5%
		NIST SRM1951c(AK)	1.0%
		JCCRM 211-3	1.3%
		JCCRM 211-3(AK)	1.3%
Triglyceride (mg/dL) :	80—150	NIST SRM1951c(FG 含)	2.5%
		JCCRM 224-8	2.4%
HDL-cholesterol (mg/dL) :	40—80	NIST SRM1951c	3.7%
		JCCRM 224-8	2.5%
LDL- cholesterol (mg/dL) :	80—160	NIST CRM1951c	2.3%
		JCCRM 224-8	2.9%

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B Biological and clinical properties

B2 Clinical chemistry

B2.3 Enzymes

- Type of reference material : Non-certified reference material,
Unfit for metrological traceability
- Name of reference material : Multianalyte Conventional Reference Material : MacRM-001
- Test method for each property:
Aspartate transaminase (AST): JSCC standard method
Alanine transaminase (ALT): JSCC standard method
Alkaline Phosphatase (ALP) : JSCC standard method
Lactate dehydrogenase (LD) :JSCC standard method
Amylase : JSCC standard method
Creatine Kinase (CK) : JSCC standard method
 γ -glutamyltransferase (γ -GT) :JSCC standard method
Cholinesterase (ChE): JSCC standard method
- Range of property values, Origin CRM, the expanded uncertainties of property values($k=2$)

Aspartate transaminase (AST) (U/L) :	100—200	JCCLS CRM-001c	2.7%
Alanine transaminase (ALT) (U/L) :	100—200	JCCLS CRM-001c	3.0%
Alkaline Phosphatase (ALP) (U/L) :	300—600	JCCLS CRM-001c	3.5%
Lactate dehydrogenase (LD) (U/L) :	300—600	JCCLS CRM-001c	2.3%



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amylase (U/L) :			
250—550	JCCLS CRM-001c		2.9%
Creatine Kinase (CK) (U/L) :			
300—600	JCCLS CRM-001c		2.8%
γ -glutamyltransferase (γ -GT) (U/L) :			
100—200	JCCLS CRM-001c		3.4%
Cholinesterase (ChE) (U/L) :			
250—500	JCCLS CRM-002c		2.1%

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B Biological and clinical properties

B2 Clinical chemistry

B2.5 Electrolytes and Trace elements

- Type of reference material : Non-certified reference material,
Unfit for metrological traceability
- Name of reference material : Multianalyte Conventional Reference Material : MacRM-001
- Test method for each property:
Iron : Nitroso-PSAP method、Bathophenanthroline method、Ferene dye method
Na : Ion selective electrode method
K : Ion selective electrode method
Cl : Ion selective electrode method
Ca : Arsenazo III method、Enzyme method、MXB method、
Chlorophosphonazo III method

Inorganic phosphorus : Enzyme method

Mg : Enzyme method

- Range of property values, Origin CRM, the expanded uncertainties of property values ($k=2$)

Iron ($\mu\text{g/dL}$) :	100—200	NIST SRM37	1.7%
		JCCRM 322-5	4.1%
Na (mmol/L) :	135—150	JCCRM 111-6	0.5%
K (mmol/L) :	3.5—5.0	JCCRM 111-6	0.7%
Cl (mmol/L) :	95—110	JCCRM 111-6	0.5%
Ca (mg/dL) :	8.5—10.5	NIST SRM915b	2.0%
		JCCRM 321-7	2.0%
Inorganic phosphorus (mg/dL) :	5.0—10.0	NIST SRM200b	1.3%
		JCCRM 324-4	2.7%
Mg (mg/dL) : 2.0—5.0		NIST SRM929a	2.2%
		JCCRM 321-7	2.6%

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B Biological and clinical properties

B2 Clinical chemistry

B2.6 Carbohydrates

- Type of reference material : Non-certified reference material,
Unfit for metrological traceability
- Name of reference material : Multianalyte Conventional Reference Material : MacRM-001
- Test method for each property:
Glucose : HK method, GOD electrode method, GluK method, GluDH method
- Range of property values, Origin CRM, the expanded uncertainties of property values($k=2$)
Glucose (mg/dL) : 100—300 NIST SRM917c 1.3%
JCCRM521-12 1.5%

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B Biological and clinical properties

B2 Clinical chemistry

B2.7 Non-protein Nitrogens

- Type of reference material : Non-certified reference material,
Unfit for metrological traceability
- Name of reference material : Multianalyte Conventional Reference Material : MacRM-001
- Test method for each property:
Uric acid : Uricase POD method, Uricase • UV method
Urea nitrogen : Urease•GLDH method (Ammonia elimination method),
Urease•GLDH•ICDH method (Ammonia elimination method),
Urease•LED method (Ammonia avoidance)
Creatine : Enzyme method
Total bilirubin : Vanadic acid oxidation method, Enzyme method,
Nitrous acid oxidation method
- Range of property values, Origin CRM, the expanded uncertainties of property values($k=2$)
Uric acid (mg/dL): 6.0—10.0 NIST SRM913b 1.4%
JCCRM521-12 1.8%
Uric acid (mg/dL): 20—50 NIST SRM912a 1.9%
JCCRM521-12 2.5%
Creatine (mg/dL): 2.0—5.0 NIST SRM914a 1.5%
JCCRM 521-12 4.1%

Total bilirubin (mg/dL) : 2.0—6.0 NIST SRM916 5.1%

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