



Reference Material Producer

Accreditation Certificate

Accreditation No.RMP00020

ILAC-MRA

Japanese Committee for Clinical Laboratory Standards

2-7-13, Uchikanda, Chiyoda-ku, Tokyo, 101-0047 Japan

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

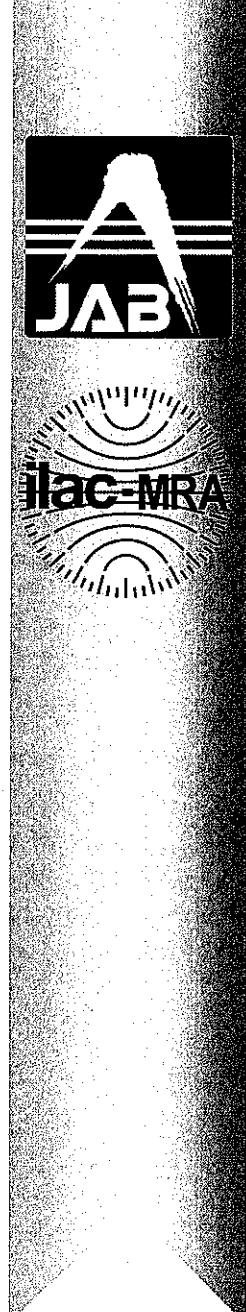
Applicable accreditation criteria	: JIS Q 17034:2018 (ISO 17034:2016)
Scope of accreditation	: As described in the appendix.
Premises covered by accreditation	: As described in the appendix.
Expiry date of accreditation	: March 31, 2025

Revised
Renewed
Initial accreditation

May 31, 2022
March 29, 2021
March 29, 2013

Y. Iizuka
Y. Iizuka, President

Japan Accreditation Board



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Japanese Committee for Clinical Laboratory Standards

Name of reference material producer	Japanese Committee for Clinical Laboratory Standards																																							
Address	Zip 101-0047	Address 2-7-13, Uchikanda, Chiyoda-ku, Tokyo, 101-0047 Japan																																						
• Applied Scope of Accreditation Code of Field	B Biological and clinical properties B2 Clinical chemistry B2.3 Enzymes																																							
Category																																								
Class (1)																																								
Class (2)																																								
• Type of reference Material	<ul style="list-style-type: none"> Type of reference material : Certified reference material 																																							
• Name of reference material	<ul style="list-style-type: none"> Name of reference material : Reference standard : JSCC Enzyme 																																							
• Test method	<ul style="list-style-type: none"> Test method : JSCC consensus method and JCCLS standard method for enzyme activity measurement Additionally, ALP and LD were determined by JCCLS standard operation procedure for enzyme activity measurement based on IFCC standard method. 																																							
• Range of property values	<ul style="list-style-type: none"> Range of property values, the expanded uncertainties of property values($k=2$) 																																							
• The expanded uncertainties of property values	<table> <tbody> <tr> <td>Aspartate transaminase (AST) :</td> <td>100U/L-200U/L</td> <td>2.4%</td> <td></td> </tr> <tr> <td>Alanine transaminase (ALT) :</td> <td>100U/L-200U/L</td> <td>2.4%</td> <td></td> </tr> <tr> <td>Creatine Kinase (CK):</td> <td>300U/L-600U/L</td> <td>2.2%</td> <td></td> </tr> <tr> <td>Alkaline Phosphatase (ALP) :</td> <td>300U/L-600U/L</td> <td>3.0%</td> <td></td> </tr> <tr> <td></td> <td>: ¹⁾108U/L-217U/L</td> <td>3.9%</td> <td></td> </tr> <tr> <td>Lactate dehydrogenase (LD) :</td> <td>300U/L-600U/L</td> <td>1.9%</td> <td></td> </tr> <tr> <td></td> <td>: ¹⁾318U/L-635U/L</td> <td>2.5%</td> <td></td> </tr> <tr> <td>γ-glutamyltransferase (γ-GT) :</td> <td>100U/L-200U/L</td> <td>3.2%</td> <td></td> </tr> <tr> <td>amylase :</td> <td>250U/L-550U/L</td> <td>2.5%</td> <td></td> </tr> </tbody> </table>				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%			: ¹⁾ 108U/L-217U/L	3.9%		Lactate dehydrogenase (LD) :	300U/L-600U/L	1.9%			: ¹⁾ 318U/L-635U/L	2.5%		γ -glutamyltransferase (γ -GT) :	100U/L-200U/L	3.2%		amylase :	250U/L-550U/L	2.5%	
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<ul style="list-style-type: none"> ▪ Applied Scope of Accreditation Code of Field <table border="0"> <tr> <td style="vertical-align: top; padding-right: 10px;">Category</td> <td>B Biological and clinical properties</td> </tr> <tr> <td>Class (1)</td> <td>B2 Clinical chemistry</td> </tr> <tr> <td>Class (2)</td> <td>B2.1 Proteins</td> </tr> </table>	Category	B Biological and clinical properties	Class (1)	B2 Clinical chemistry	Class (2)	B2.1 Proteins	<ul style="list-style-type: none"> ▪ Type of reference Material ▪ Name of reference material ▪ Test method ▪ Range of property values ▪ The expanded uncertainties of property values <p>B Biological and clinical properties</p> <p>B2 Clinical chemistry</p> <p>B2.1 Proteins</p> <ul style="list-style-type: none"> ▪ 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: <ul style="list-style-type: none"> C-reactive protein (CRP) :Latex terbidimetric 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($k=2$) <table border="0"> <tr> <td>C-reactive protein (CRP) (mg/dL) :</td> <td>3.0 – 5.0</td> <td>IRMM ERM-DA474</td> <td>6.6%</td> </tr> <tr> <td>Albumin (g/dL) :</td> <td>4.0 – 5.0</td> <td>IRMM ERM-DA470k</td> <td>3.6%</td> </tr> <tr> <td>IgG (mg/dL) :</td> <td>800 – 1600</td> <td>IRMM ERM-DA470k</td> <td>2.5%</td> </tr> <tr> <td>IgA (mg/dL) :</td> <td>200 – 500</td> <td>IRMM ERM-DA470k</td> <td>3.2%</td> </tr> <tr> <td>IgM (mg/dL) :</td> <td>50 – 200</td> <td>IRMM ERM-DA470k</td> <td>4.3%</td> </tr> <tr> <td>Total protein (mg/dL) :</td> <td>6.5 – 8.5</td> <td>NIST SRM927</td> <td>2.2%</td> </tr> </table> <p>An expanded uncertainty represents Calibration and Measurement Capability (CMC) at approximately 95 % level of Confidence, including homogeneity and stability of the material</p>	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%
Category	B Biological and clinical properties																														
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• Applied Scope of Accreditation Code of Field	B Biological and clinical properties B2 Clinical chemistry B2.2 Lipids and Lipoproteins		
Category			
Class (1)			
Class (2)			
• Type of reference Material	• Type of reference material : Non-certified reference material, Unfit for metrological traceability		
• Name of reference material	• Name of reference material : Multianalyte Conventional Reference Material : MacRM-001		
• Test method	• 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	• Range of property values, Origin CRM, the expanded uncertainties of property values($k=2$)		
• The expanded uncertainties of property values	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(including FG)	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%
An expanded uncertainty represents Calibration and Measurement Capability (CMC) at approximately 95 % level of Confidence, including homogeneity and stability of the material			

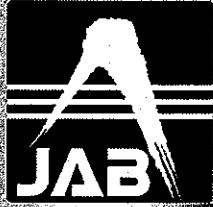


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<ul style="list-style-type: none">• Applied Scope of Accreditation Code of Field	<p>B Biological and clinical properties</p> <p>B2 Clinical chemistry</p> <p>B2.3 Enzymes</p>															
<ul style="list-style-type: none">• Category																
<ul style="list-style-type: none">Class (1)																
<ul style="list-style-type: none">Class (2)																
<ul style="list-style-type: none">• Type of reference Material	<ul style="list-style-type: none">• Type of reference material : Non-certified reference material, Unfit for metrological traceability															
<ul style="list-style-type: none">• Name of reference material	<ul style="list-style-type: none">• Name of reference material : Multianalyte Conventional Reference Material : MacRM-001															
<ul style="list-style-type: none">• Test method	<ul style="list-style-type: none">• Test method for each property:<ul style="list-style-type: none">Aspartate transaminase (AST) : JSCC standard methodAlanine transaminase (ALT) : JSCC standard methodAlkaline Phosphatase (ALP) : IFCC standard methodLactate dehydrogenase (LD) : IFCC standard methodAmylase : JSCC standard methodCreatine Kinase (CK) : JSCC standard methodγ-glutamyltransferase (γ-GT) : JSCC standard methodCholinesterase (ChE) : JSCC standard method															
<ul style="list-style-type: none">• Range of property values	<ul style="list-style-type: none">• Range of property values, Origin CRM, the expanded uncertainties of property values($k=2$)															
<ul style="list-style-type: none">• The expanded uncertainties of property values	<p>Aspartate transaminase (AST) (U/L) :</p> <table><tr><td>100—200</td><td>JCCLS CRM-001d</td><td>2.7%</td></tr></table> <p>Alanine transaminase (ALT) (U/L) :</p> <table><tr><td>100—200</td><td>JCCLS CRM-001d</td><td>3.0%</td></tr></table> <p>Alkaline Phosphatase (ALP) (U/L) :</p> <table><tr><td>100—210</td><td>JCCLS CRM-001d</td><td>4.2%</td></tr></table> <p>Lactate dehydrogenase (LD) (U/L) :</p> <table><tr><td>300—620</td><td>JCCLS CRM-001d</td><td>2.7%</td></tr></table> <p>amylase (U/L) :</p> <table><tr><td>250—550</td><td>JCCLS CRM-001d</td><td>2.9%</td></tr></table>	100—200	JCCLS CRM-001d	2.7%	100—200	JCCLS CRM-001d	3.0%	100—210	JCCLS CRM-001d	4.2%	300—620	JCCLS CRM-001d	2.7%	250—550	JCCLS CRM-001d	2.9%
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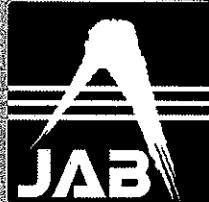
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Creatine Kinase (CK) (U/L) :	300 – 600	JCCLS CRM-001d	2.8%
γ -glutamyltransferase (γ -GT) (U/L) :	100 – 200	JCCLS CRM-001d	3.4%
Cholinesterase (ChE) (U/L) :	250 – 500	JCCLS CRM-002d	2.1%

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

• Applied Scope of Accreditation Code of Field	B Biological and clinical properties B2 Clinical chemistry B2.5 Electrolytes and Trace elements
Category	
Class (1)	
Class (2)	
• Type of reference Material	• Type of reference material : Non-certified reference material, Unfit for metrological traceability
• Name of reference material	• Name of reference material : Multianalyte Conventional Reference Material : MacRM-001
• Test method	• 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 : ArsenazoIII method, Enzyme method, MXBmethod, ChlorophosphonazoIII method Inorganic phosphorus : Enzyme method Mg : Enzyme method
• Range of property values	• Range of property values, Origin CRM, the expanded uncertainties of property values($k=2$)



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The expanded uncertainties of property values	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%
Applied Scope of Accreditation Code of Field	Mg (mg/dL) :	2.0—5.0	NIST SRM929a	2.2%
			JCCRM 321-7	2.6%
	An expanded uncertainty represents Calibration and Measurement Capability (CMC) at approximately 95 % level of Confidence, including homogeneity and stability of the material			
	Category	B Biological and clinical properties		
	Class (1)	B2 Clinical chemistry		
	Class (2)	B2.6 Carbohydrates		
	Type of reference Material	Type of reference material : Non-certified reference material, Unfit for metrological traceability		
	Name of reference material	Name of reference material : Multianalyte Conventional Reference Material : MacRM-001		
	Test method	Test method for each property: Glucose : HK method、GOD electrode method、GluK method、GluDH method		
Range of property values	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%
The expanded uncertainties of				



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property values	An expanded uncertainty represents Calibration and Measurement Capability (CMC) at approximately 95 % level of Confidence, including homogeneity and stability of the material
• Applied Scope of Accreditation Code of Field	• Classification code : B2.7 B Biological and clinical properties B2 Clinical chemistry B2.7 Non-protein Nitrogens
Category Class (1) Class (2)	
• Type of reference Material	• Type of reference material : Non-certified reference material, Unfit for metrological traceability
• Name of reference material	• Name of reference material : Multianalyte Conventional Reference Material : MacRM-001
• Test method	• 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	• Range of property values, Origin CRM, the expanded uncertainties of property values($k=2$)
• The expanded uncertainties of property values	Uric acid (mg/dL): 6.0—10.0 NIST SRM913b 1.4% Uric acid (mg/dL): 20—50 NIST SRM912a 1.9% Uric acid (mg/dL): 20—50 JCCRM521-12 1.8% Uric acid (mg/dL): 20—50 JCCRM521-12 2.5% Creatine (mg/dL): 2.0—5.0 NIST SRM914a 1.5% Creatine (mg/dL): 2.0—5.0 JCCRM 521-12 4.1%



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