



Reference Material Producer

# Accreditation Certificate

Accreditation No. RMP00020



***Japanese Committee for Clinical Laboratory Standards***

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

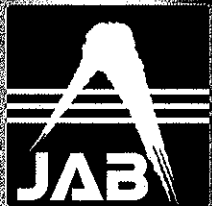
meets the following criteria. On the basis of this, Japan Accreditation Board (JAB) grants accreditation to the said reference material producer.

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

Renewed (2)	March 29, 2021
Initial accreditation	March 29, 2013

Y. Mizuka, President

## Japan Accreditation Board



# Accreditation Certificate Appendix

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Accreditation No. RMP00020



## Japanese Committee for Clinical Laboratory Standards

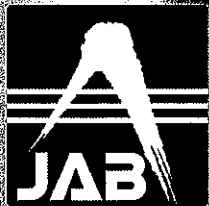
Name of reference material producer	Japanese Committee for Clinical Laboratory Standards																														
Address	Zip	101-0047	Address	2-7-13, Uchikanda, Chiyoda-ku, Tokyo, 101-0047 Japan																											
<ul style="list-style-type: none"> <li>• Applied Scope of Accreditation Code of Field</li> <li>Category</li> <li>Class (1)</li> <li>Class (2)</li> <li>• Type of reference Material</li> <li>• Name of reference material</li> <li>• Test method</li> <li>• Range of property values</li> <li>• The expanded uncertainties of property values</li> </ul>	<p>B Biological and clinical properties B2 Clinical chemistry B2.3 Enzymes</p> <ul style="list-style-type: none"> <li>• Type of reference material : Certified reference material</li> <li>• Name of reference material : Reference standard : JSCC Enzyme</li> <li>• 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.</li> <li>• Range of property values, the expanded uncertainties of property values (<math>k=2</math>) <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 2px;">Aspartate transaminase (AST) :</td> <td style="padding: 2px;">100U/L-200U/L</td> <td style="padding: 2px;">2.4%</td> </tr> <tr> <td style="padding: 2px;">Alanine transaminase (ALT) :</td> <td style="padding: 2px;">100U/L-200U/L</td> <td style="padding: 2px;">2.4%</td> </tr> <tr> <td style="padding: 2px;">Creatine Kinase (CK):</td> <td style="padding: 2px;">300U/L-600U/L</td> <td style="padding: 2px;">2.2%</td> </tr> <tr> <td style="padding: 2px;">Alkaline Phosphatase (ALP) :</td> <td style="padding: 2px;">300U/L-600U/L</td> <td style="padding: 2px;">3.0%</td> </tr> <tr> <td style="padding: 2px;"></td> <td style="padding: 2px;"><sup>1)</sup>108U/L-217U/L</td> <td style="padding: 2px;">3.9%</td> </tr> <tr> <td style="padding: 2px;">Lactate dehydrogenase (LD) :</td> <td style="padding: 2px;">300U/L-600U/L</td> <td style="padding: 2px;">1.9%</td> </tr> <tr> <td style="padding: 2px;"></td> <td style="padding: 2px;"><sup>1)</sup>318U/L-635U/L</td> <td style="padding: 2px;">2.5%</td> </tr> <tr> <td style="padding: 2px;"><math>\gamma</math>-glutamyltransferase (<math>\gamma</math>-GT) :</td> <td style="padding: 2px;">100U/L-200U/L</td> <td style="padding: 2px;">3.2%</td> </tr> <tr> <td style="padding: 2px;">amylase :</td> <td style="padding: 2px;">250U/L-550U/L</td> <td style="padding: 2px;">2.5%</td> </tr> </table> </li> </ul> <p>An expanded uncertainty represents Calibration and Measurement Capability (CMC) at approximately 95 % level of Confidence, including homogeneity and stability of the material. <sup>1)</sup> values were determined by JCCLS standard operation procedure for enzyme activity measurement based on IFCC standard method.</p>				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%		<sup>1)</sup> 108U/L-217U/L	3.9%	Lactate dehydrogenase (LD) :	300U/L-600U/L	1.9%		<sup>1)</sup> 318U/L-635U/L	2.5%	$\gamma$ -glutamyltransferase ( $\gamma$ -GT) :	100U/L-200U/L	3.2%	amylase :	250U/L-550U/L	2.5%
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• Applied Scope of Accreditation Code of Field	B Biological and clinical properties B2 Clinical chemistry B2.1 Proteins																								
• 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 : Multianalyte Conventional Reference Material : MacRM-001																								
• Name of reference material	• Test method for each property: C-reactive protein (CRP) : Latex turbidimetric assay Albumin : modified BCP assay																								
• Test method	IgG : Immunoturbidimetric assay, nephelometric immunoassay IgA : Immunoturbidimetric assay, nephelometric immunoassay IgM : Immunoturbidimetric assay, nephelometric immunoassay Total protein : Biuret test																								
• Range of property values	• Range of property values, Origin CRM, the expanded uncertainties of property values ( $k=2$ )																								
• The expanded uncertainties of property values	<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>	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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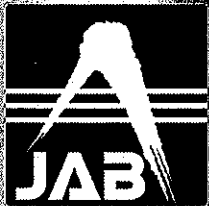
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<ul style="list-style-type: none"> <li>• Applied Scope of Accreditation Code of Field</li> <li>Category</li> <li>Class (1)</li> <li>Class (2)</li> <li>• Type of reference Material</li> <li>• Name of reference material</li> <li>• Test method</li> <li>• Range of property values</li> <li>• The expanded uncertainties of property values</li> </ul>	<p>B Biological and clinical properties B2 Clinical chemistry B2.3 Enzymes</p> <ul style="list-style-type: none"> <li>• Type of reference material : Non-certified reference material, Unfit for metrological traceability</li> <li>• Name of reference material : Multianalyte Conventional Reference Material : MacRM-001</li> <li>• Test method for each property: <ul style="list-style-type: none"> <li>Aspartate transaminase (AST): JSCC standard method</li> <li>Alanine transaminase (ALT): JSCC standard method</li> <li>Alkaline Phosphatase (ALP) : JSCC standard method</li> <li>Lactate dehydrogenase (LD) :JSCC standard method</li> <li>Amylase : JSCC standard method</li> <li>Creatine Kinase (CK) : JSCC standard method</li> <li><math>\gamma</math>-glutamyltransferase (<math>\gamma</math>-GT) :JSCC standard method</li> <li>Cholinesterase (ChE): JSCC standard method</li> </ul> </li> <li>• Range of property values, Origin CRM, the expanded uncertainties of property values(<math>k=2</math>) <ul style="list-style-type: none"> <li>Aspartate transaminase (AST) (U/L) : 100—200 JCCLS CRM-001c 2.7%</li> <li>Alanine transaminase (ALT) (U/L) : 100—200 JCCLS CRM-001c 3.0%</li> <li>Alkaline Phosphatase (ALP) (U/L) : 300—600 JCCLS CRM-001c 3.5%</li> <li>Lactate dehydrogenase (LD) (U/L) : 300—600 JCCLS CRM-001c 2.3%</li> <li>amylase (U/L) : 250—550 JCCLS CRM-001c 2.9%</li> <li>Creatine Kinase (CK) (U/L) :</li> </ul> </li> </ul>
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	<p>300 – 600 JCCLS CRM-001c 2.8%</p> <p><math>\gamma</math>-glutamyltransferase (<math>\gamma</math>-GT) (U/L) :</p> <p>100 – 200 JCCLS CRM-001c 3.4%</p> <p>Cholinesterase (ChE) (U/L) :</p> <p>250 – 500 JCCLS CRM-002c 2.1%</p> <p>An expanded uncertainty represents Calibration and Measurement Capability (CMC) at approximately 95 % level of Confidence, including homogeneity and stability of the material</p>												
<ul style="list-style-type: none"> <li>• Applied Scope of Accreditation Code of Field</li> <li>Category</li> <li>Class (1)</li> <li>Class (2)</li> <li>• Type of reference Material</li> <li>• Name of reference material</li> <li>• Test method</li> <li>• Range of property values</li> </ul>	<p>B Biological and clinical properties</p> <p>B2 Clinical chemistry</p> <p>B2.5 Electrolytes and Trace elements</p> <ul style="list-style-type: none"> <li>• Type of reference material : Non-certified reference material, Unfit for metrological traceability</li> <li>• Name of reference material : Multianalyte Conventional Reference Material : MacRM-001</li> <li>• Test method for each property:           <ul style="list-style-type: none"> <li>Iron : Nitroso-PSAP method, Bathophenanthroline method, Ferene dye method</li> <li>Na : Ion selective electrode method</li> <li>K : Ion selective electrode method</li> <li>Cl : Ion selective electrode method</li> <li>Ca : Arsenazo III method, Enzyme method, MXBmethod, Chlorophosphonazo III method</li> <li>Inorganic phosphorus : Enzyme method</li> <li>Mg : Enzyme method</li> </ul> </li> <li>• Range of property values, Origin CRM, the expanded uncertainties of property values(<math>k=2</math>)           <table border="0" style="width: 100%; margin-top: 10px;"> <tr> <td style="width: 30%;">Iron (<math>\mu\text{g/dL}</math>) :</td> <td style="width: 20%;">100 – 200</td> <td style="width: 30%;">NIST SRM37</td> <td style="width: 20%;">1.7%</td> </tr> <tr> <td></td> <td></td> <td>JCCRM 322-5</td> <td>4.1%</td> </tr> <tr> <td>Na (mmol/L) :</td> <td>135 – 150</td> <td>JCCRM 111-6</td> <td>0.5%</td> </tr> </table> </li> </ul>	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%
Iron ( $\mu\text{g/dL}$ ) :	100 – 200	NIST SRM37	1.7%										
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<ul style="list-style-type: none"> <li>The expanded uncertainties of property values</li> </ul>	<table border="0"> <tr> <td>K (mmol/L) :</td> <td>3.5 – 5.0</td> <td>JCCRM 111-6</td> <td>0.7%</td> </tr> <tr> <td>Cl (mmol/L) :</td> <td>95 – 110</td> <td>JCCRM 111-6</td> <td>0.5%</td> </tr> <tr> <td>Ca (mg/dL) :</td> <td>8.5 – 10.5</td> <td>NIST SRM915b</td> <td>2.0%</td> </tr> <tr> <td></td> <td></td> <td>JCCRM 321-7</td> <td>2.0%</td> </tr> <tr> <td>Inorganic phosphorus (mg/dL) :</td> <td>5.0 – 10.0</td> <td>NIST SRM200b</td> <td>1.3%</td> </tr> <tr> <td></td> <td></td> <td>JCCRM 324-4</td> <td>2.7%</td> </tr> <tr> <td>Mg (mg/dL) :2.0–5.0</td> <td></td> <td>NIST SRM929a</td> <td>2.2%</td> </tr> <tr> <td></td> <td></td> <td>JCCRM 321-7</td> <td>2.6%</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>	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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<ul style="list-style-type: none"> <li>Applied Scope of Accreditation Code of Field</li> <li>Category</li> <li>Class (1)</li> <li>Class (2)</li> <li>Type of reference Material</li> <li>Name of reference material</li> <li>Test method</li> <li>Range of property values</li> <li>The expanded uncertainties of property values</li> </ul>	<p>B Biological and clinical properties B2 Clinical chemistry B2.6 Carbohydrates</p> <ul style="list-style-type: none"> <li>Type of reference material : Non-certified reference material, Unfit for metrological traceability</li> <li>Name of reference material : Multianalyte Conventional Reference Material : MacRM-001</li> <li>Test method for each property: Glucose : HK method, GOD electrode method, GluK method, GluDH method</li> <li>Range of property values, Origin CRM, the expanded uncertainties of property values(<math>k=2</math>) Glucose (mg/dL) : 100 – 300 NIST SRM917c 1.3% JCCRM521-12 1.5%</li> </ul> <p>An expanded uncertainty represents Calibration and Measurement Capability (CMC) at approximately 95 % level of Confidence, including homogeneity and stability of the material</p>																																



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<ul style="list-style-type: none"> <li>Applied Scope of Accreditation Code of Field</li> <li>Category</li> <li>Class (1)</li> <li>Class (2)</li> <li>Type of reference Material</li> <li>Name of reference material</li> <li>Test method</li> </ul>	<ul style="list-style-type: none"> <li>Classification code : B2.7 B Biological and clinical properties B2 Clinical chemistry B2.7 Non-protein Nitrogens</li> <li>Type of reference material : Non-certified reference material, Unfit for metrological traceability</li> <li>Name of reference material : Multianalyte Conventional Reference Material : MacRM-001</li> <li>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</li> <li>Range of property values, Origin CRM, the expanded uncertainties of property values(<math>k=2</math>) <table border="1"> <tr> <td>Uric acid (mg/dL):</td> <td>6.0 – 10.0</td> <td>NIST SRM913b</td> <td>1.4%</td> </tr> <tr> <td></td> <td></td> <td>JCCRM521-12</td> <td>1.8%</td> </tr> <tr> <td>Uric acid (mg/dL):</td> <td>20 – 50</td> <td>NIST SRM912a</td> <td>1.9%</td> </tr> <tr> <td></td> <td></td> <td>JCCRM521-12</td> <td>2.5%</td> </tr> <tr> <td>Creatine (mg/dL):</td> <td>2.0 – 5.0</td> <td>NIST SRM914a</td> <td>1.5%</td> </tr> <tr> <td></td> <td></td> <td>JCCRM 521-12</td> <td>4.1%</td> </tr> <tr> <td>Total bilirubin (mg/dL) :</td> <td>2.0 – 6.0</td> <td>NIST SRM916</td> <td>5.1%</td> </tr> </table> </li> </ul>	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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