



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

Revised	May 31, 2022
Renewed	March 29, 2021
Initial accreditation	March 29, 2013

Y. Iizuka, President

## Japan Accreditation Board



**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.</p> <p><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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<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>	<p>B Biological and clinical properties B2 Clinical chemistry B2.1 Proteins</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: 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</li> </ul>																								
<ul style="list-style-type: none"> <li>• Range of property values</li> <li>• The expanded uncertainties of property values</li> </ul>	<ul style="list-style-type: none"> <li>• Range of property values, Origin CRM, the expanded uncertainties of property values (<math>k=2</math>)</li> </ul> <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%
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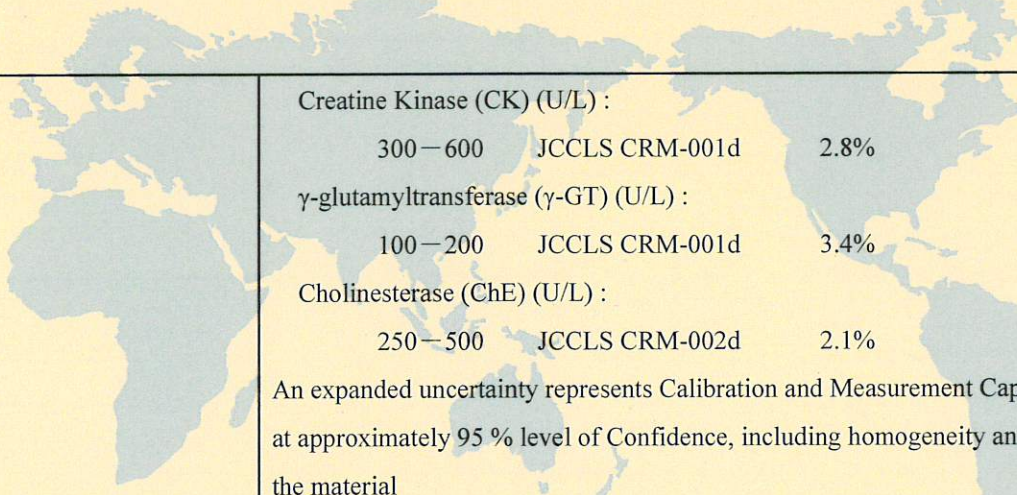


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	<p>Creatine Kinase (CK) (U/L) :</p> <p>300 – 600 JCCLS CRM-001d 2.8%</p> <p><math>\gamma</math>-glutamyltransferase (<math>\gamma</math>-GT) (U/L) :</p> <p>100 – 200 JCCLS CRM-001d 3.4%</p> <p>Cholinesterase (ChE) (U/L) :</p> <p>250 – 500 JCCLS CRM-002d 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、 MXB method, 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>)</li> </ul>



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<ul style="list-style-type: none"> <li>The expanded uncertainties of property values</li> </ul>	<table border="0"> <tr> <td>Iron (µg/dL) :</td> <td>100 – 200</td> <td>NIST SRM37</td> <td>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> <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) :</td> <td>2.0 – 5.0</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>	Iron (µg/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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property values	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"> <li>• Range of property values</li> <li>• The expanded uncertainties of property values</li> </ul>	<ul style="list-style-type: none"> <li>• Range of property values, Origin CRM, the expanded uncertainties of property values(<math>k=2</math>)</li> </ul> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%;">Uric acid (mg/dL):</td> <td style="width: 20%;">6.0 – 10.0</td> <td style="width: 30%;">NIST SRM913b</td> <td style="width: 20%;">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> </table>	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%
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***Japanese Committee for Clinical Laboratory Standards***

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