



JAB

Reference Material Producer

Accreditation Certificate

Accreditation No. RMP00020

NPO 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 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

Revised (2)	October 30, 2018
Renewed (1)	March 24, 2017
Initial accreditation	March 29, 2013

K. Chiba, Chairman
Reference Material Producer Accreditation Committee

Y. Iizuka, President
Japan Accreditation Board



JAB

NPO Japanese Committee for Clinical Laboratory Standards

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2-7-13, Uchikanda, Chiyoda-ku, Tokyo, 101-0047 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 : Reference standard : 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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B2 Clinical chemistry																																							
B2.2 Lipids and Lipoproteins																																							
<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"> 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($k=2$) <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%; vertical-align: top;">Total cholesterol (mg/dL) :</td> <td style="width: 20%; vertical-align: top;">150 – 250</td> <td style="width: 40%; vertical-align: top;"> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding-left: 20px;">NIST SRM1951c</td> <td style="text-align: right;">1.5%</td> </tr> <tr> <td style="padding-left: 20px;">NIST SRM1951c(AK)</td> <td style="text-align: right;">1.0%</td> </tr> <tr> <td style="padding-left: 20px;">JCCRM 211-3</td> <td style="text-align: right;">1.3%</td> </tr> <tr> <td style="padding-left: 20px;">JCCRM 211-3(AK)</td> <td style="text-align: right;">1.3%</td> </tr> </table> </td> <td style="width: 10%;"></td> </tr> <tr> <td style="vertical-align: top;">Triglyceride (mg/dL) :</td> <td style="vertical-align: top;">80 – 150</td> <td style="vertical-align: top;"> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding-left: 20px;">NIST SRM1951c(includingFG)</td> <td style="text-align: right;">2.5%</td> </tr> <tr> <td style="padding-left: 20px;">JCCRM 224-8</td> <td style="text-align: right;">2.4%</td> </tr> </table> </td> <td></td> </tr> <tr> <td style="vertical-align: top;">HDL-cholesterol (mg/dL) :</td> <td style="vertical-align: top;">40 – 80</td> <td style="vertical-align: top;"> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding-left: 20px;">NIST SRM1951c</td> <td style="text-align: right;">3.7%</td> </tr> <tr> <td style="padding-left: 20px;">JCCRM 224-8</td> <td style="text-align: right;">2.5%</td> </tr> </table> </td> <td></td> </tr> <tr> <td style="vertical-align: top;">LDL- cholesterol (mg/dL) :</td> <td style="vertical-align: top;">80 – 160</td> <td style="vertical-align: top;"> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding-left: 20px;">NIST CRM1951c</td> <td style="text-align: right;">2.3%</td> </tr> <tr> <td style="padding-left: 20px;">JCCRM 224-8</td> <td style="text-align: right;">2.9%</td> </tr> </table> </td> <td></td> </tr> </table> 				Total cholesterol (mg/dL) :	150 – 250	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding-left: 20px;">NIST SRM1951c</td> <td style="text-align: right;">1.5%</td> </tr> <tr> <td style="padding-left: 20px;">NIST SRM1951c(AK)</td> <td style="text-align: right;">1.0%</td> </tr> <tr> <td style="padding-left: 20px;">JCCRM 211-3</td> <td style="text-align: right;">1.3%</td> </tr> <tr> <td style="padding-left: 20px;">JCCRM 211-3(AK)</td> <td style="text-align: right;">1.3%</td> </tr> </table>	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	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding-left: 20px;">NIST SRM1951c(includingFG)</td> <td style="text-align: right;">2.5%</td> </tr> <tr> <td style="padding-left: 20px;">JCCRM 224-8</td> <td style="text-align: right;">2.4%</td> </tr> </table>	NIST SRM1951c(includingFG)	2.5%	JCCRM 224-8	2.4%		HDL-cholesterol (mg/dL) :	40 – 80	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding-left: 20px;">NIST SRM1951c</td> <td style="text-align: right;">3.7%</td> </tr> <tr> <td style="padding-left: 20px;">JCCRM 224-8</td> <td style="text-align: right;">2.5%</td> </tr> </table>	NIST SRM1951c	3.7%	JCCRM 224-8	2.5%		LDL- cholesterol (mg/dL) :	80 – 160	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding-left: 20px;">NIST CRM1951c</td> <td style="text-align: right;">2.3%</td> </tr> <tr> <td style="padding-left: 20px;">JCCRM 224-8</td> <td style="text-align: right;">2.9%</td> </tr> </table>	NIST CRM1951c	2.3%	JCCRM 224-8	2.9%	
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Accreditation Certificate Appendix

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NPO Japanese Committee for Clinical Laboratory Standards

Scope of Accreditation :

Lactate dehydrogenase (LD) (U/L) :			
300-600	JCCLS CRM-001c		2.3%
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%

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
B2.5 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 : ArsenazoIII method, Enzyme method, MXB method, ChlorophosphonazoIII 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

