Reference Material Producer

Accreditation Certificate

Accreditation No.RMP00020

PIIA 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, 2029

Revised	December 11, 2024
Renewed	April 1, 2025
Initial accreditation	March 29, 2013

Y. Miki, President

Japan Accreditation Board

Issue No. : RMP00020-20241211

Accreditation Certificate Appendix

Accreditation No. RMP00020

PIIA Japanese Committee for Clinical Laboratory Standards

Name of reference material producer	PIIA 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 Category Class (1) Class (2)	B Biological and clinical properties B2 Clinical chemistry B2.3 Enzymes
・Type of reference Material	・Type of reference material：Certified reference material
・Name of reference material	・Name of reference material：Reference standard：JSCC Enzyme
・Test method	・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 ・The expanded uncertainties of property values	・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% ：[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：255U/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. [1)] values were determined by JCCLS standard operation procedure for enzyme activity measurement based on IFCC standard method.

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・Applied Scope of Accreditation Code of Field Category Class (1) Class (2)	B Biological and clinical properties B2 Clinical chemistry B2.1 Proteins
・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: C-reactive protein (CRP) :Latex terbidimetric assay Albumin : modified BCP assay IgG :Immunoturbidimetric assay IgA : Immunoturbidimetric assay IgM : Immunoturbidimetric assay Total protein : Biuret test
・Range of property values ・The expanded uncertainties of property values	・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 6.5% Albumin (g/dL) : 4.0－5.0 IRMM ERM-DA470k 3.6% IgG (mg/dL) : 800－1600 IRMM ERM-DA470k 2.4% IgA (mg/dL) : 200－500 IRMM ERM-DA470k 3.3% IgM (mg/dL) : 50－200 IRMM ERM-DA470k 4.5% Total protein (mg/dL) : 6.5－8.5 NIST SRM927 4.2% 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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・Applied Scope of Accreditation Code of Field Category Class (1) Class (2)	B Biological and clinical properties B2 Clinical chemistry B2.2 Lipids and Lipoproteins
・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 ・The expanded uncertainties of property values	・Range of property values, Origin CRM, the expanded uncertainties of property values(k=2) Total cholesterol (mg/dL)：150－250 JCCRM 211-8 1.7% JCCRM 211-8 (AK) 1.8% Triglyceride (mg/dL)： 80－160 JCCRM 211-16 3.5% HDL-cholesterol (mg/dL)： 40－80 JCCRM 224-16 3.1% LDL- cholesterol (mg/dL)： 80－160 JCCRM 224-16 2.5% 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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・Applied Scope of Accreditation Code of Field Category Class (1) Class (2)	B Biological and clinical properties B2 Clinical chemistry B2.3 Enzymes
・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: Aspartate transaminase (AST): JSCC standard method Alanine transaminase (ALT): JSCC standard method Alkaline Phosphatase（ALP）: IFCC standard method Lactate dehydrogenase（LD）:IFCC 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 ・The expanded uncertainties of property values	・Range of property values, Origin CRM, the expanded uncertainties of property values(k=2) Aspartate transaminase (AST) (U/L) : 100－200 JCCLS CRM-001d 2.7% Alanine transaminase (ALT) (U/L) : 100－200 JCCLS CRM-001d 3.4% Alkaline Phosphatase（ALP） (U/L) : 100－210 JCCLS CRM-001d 4.2% Lactate dehydrogenase（LD） (U/L) : 300－620 JCCLS CRM-001d 2.8% amylase (U/L) : 250－500 JCCLS CRM-001d 2.9% Creatine Kinase (CK) (U/L) : 300－600 JCCLS CRM-001d 2.8%

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	γ -glutamyltransferase (γ-GT) (U/L) : 100－200 JCCLS CRM-001d 3.5% Cholinesterase (ChE) (U/L) : 250－500 JCCLS CRM-002d 2.0% 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 Category Class (1) Class (2)	B Biological and clinical properties B2 Clinical chemistry B2.5 Electrolytes and Trace elements
・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 Na： Ion selective electrode method K： Ion selective electrode method Cl： Ion selective electrode method Ca： Arsenazo Ⅲ method, Enzyme method、MXBmethod, Chlorophosphonazo Ⅲ method Inorganic phosphorus： Enzyme method Mg：Enzyme method
・Range of property values ・The expanded uncertainties of property values	・Range of property values, Origin CRM, the expanded uncertainties of property values(k=2) Iron (μg/dL)： 100－200 NIST SRM37 2.2% JCCRM 322-7 3.2% Na (mmol/L) ： 135－150 JCCRM 321-8 0.7% K (mmol/L)： 3.5－5.0 JCCRM 321-8 0.9%

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	Cl (mmol/L) : 95 －110 JCCRM 321-8 0.9% Ca (mg/dL) : 8.5－10.5 NIST SRM915b 1.7% JCCRM 321-8 1.5% Inorganic phosphorus (mg/dL) : 5.0－10.0 NIST SRM200b 1.1% JCCRM 324-6 2.1% Mg (mg/dL) : 2.0－5.0 NIST SRM929a 3.1% JCCRM 321-8 2.9% An expanded uncertainty represents Calibration and Measurement Capability (CMC) at approximately 95 % level of Confidence, including homogeneity and stability of the material
・Applied Scope of Accreditation Code of Field Category Class (1) Class (2)	B Biological and clinical properties B2 Clinical chemistry 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 ・The expanded uncertainties 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% JCCRM 521-14 1.7% 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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・Applied Scope of Accreditation Code of Field Category Class (1) Class (2)	・Classification code：B2.7 B Biological and clinical properties B2 Clinical chemistry B2.7 Non-protein Nitrogens
・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 ：Ammonia elimination method, Ammonia avoidance method Creatine ：Enzyme method Total bilirubin ：Vanadic acid oxidation method, Enzyme method,
・Range of property values ・The expanded uncertainties of property values	・Range of property values, Origin CRM, the expanded uncertainties of property values(k=2) Uric acid (mg/dL): 6.0－10.0 NIST SRM913b 1.5% JCCRM 521-14 1.6% Urea Nitrogen (mg/dL): 20－50 NIST SRM912a 2.1% JCCRM 521-14 3.1% Creatine (mg/dL): 2.0－5.0 NIST SRM914a 1.5% JCCRM 521-14 3.0% Total bilirubin (mg/dL)： 2.0－6.0 NIST SRM916 5.4% 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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・Applied Scope of Accreditation Code of Field Category Class (1) Class (2)	B Biological and clinical properties B2 Clinical chemistry B2.1 Proteins
・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-002
・Test method	・Test method for each property: C-reactive protein (CRP) :Latex terbidimetric assay Albumin : modified BCP assay IgG :Immunoturbidimetric assay IgA : Immunoturbidimetric assay IgM : Immunoturbidimetric assay Total protein : Biuret test
・Range of property values ・The expanded uncertainties of property values	・Range of property values, Origin CRM, the expanded uncertainties of property values(k=2) C-reactive protein (CRP) (mg/dL) : 1) 0.20-0.60 IRMM ERM-DA474 7.3% 2) 1.00-2.00 IRMM ERM-DA474 6.9% 3) 3.00-5.00 IRMM ERM-DA474 6.5% Albumin (g/dL) : 1) 4.5-6.0 IRMM ERM-DA470k 3.7% 2) 3.5-4.9 IRMM ERM-DA470k 3.6% 3) 2.5-3.7 IRMM ERM-DA470k 3.8% IgG (mg/dL) : 1) 1100-1700 IRMM ERM-DA470k 2.4% 2) 800-1400 IRMM ERM-DA470k 2.4% 3) 600-1100 IRMM ERM-DA470k 2.4% IgA (mg/dL) : 1) 150-350 IRMM ERM-DA470k 3.7% 2) 120-280 IRMM ERM-DA470k 3.8%

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		3) 90-210	IRMM ERM-DA470k	3.5%
	IgM (mg/dL) :	1) 50-160	IRMM ERM-DA470k	4.8%
		2) 40-130	IRMM ERM-DA470k	4.9%
		3) 35-95	IRMM ERM-DA470k	4.9%
	Total protein (mg/dL) :	1) 7.5-9.0	NIST SRM927	4.2%
		2) 5.5-7.5	NIST SRM927	4.2%
		3) 4.0-5.5	NIST SRM927	4.2%
	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 Category Class (1) Class (2)	B Biological and clinical properties B2 Clinical chemistry B2.2 Lipids and Lipoproteins			
・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-002			
・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) :	1) 180-250	JCCRM 211-8	2.1%
			JCCRM 211-8(AK)	2.2%
		2) 140-200	JCCRM 211-8	2.0%

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			JCCRM 211-8(AK)	2.1%
		3) 100-150	JCCRM 211-8	1.9%
			JCCRM 211-8(AK)	2.0%
	Triglyceride (mg/dL) :	1) 80-200	JCCRM 211-8	3.4%
		2) 60-150	JCCRM 211-8	4.0%
		3) 40-100	JCCRM 211-8	4.0%
	HDL-cholesterol (mg/dL) :	1) 50-100	JCCRM 224-16	3.1%
		2) 35-85	JCCRM 224-16	2.8%
		3) 25-65	JCCRM 224-16	2.8%
	LDL- cholesterol (mg/dL) :	1) 80-160	JCCRM 224-16	2.5%
		2) 65-125	JCCRM 224-16	2.6%
		3) 45-95	JCCRM 224-16	2.7%
	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 Category Class (1) Class (2)	B Biological and clinical properties B2 Clinical chemistry B2.3 Enzymes			
・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-002			
・Test method	・Test method for each property: Aspartate transaminase (AST): JSCC standard method Alanine transaminase (ALT): JSCC standard method Alkaline Phosphatase（ALP）: IFCC standard method			

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	Lactate dehydrogenase（LD）:IFCC 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 ・The expanded uncertainties of property values	・Range of property values, Origin CRM, the expanded uncertainties of property values(k=2) Aspartate transaminase (AST) (U/L) : 1) 40-100 JCCLS CRM-001d 3.0% 2) 10-40 JCCLS CRM-001d 5.8% 3) 100-250 JCCLS CRM-001d 2.7% Alanine transaminase (ALT) (U/L) : 1) 40-100 JCCLS CRM-001d 5.4% 2) 10-40 JCCLS CRM-001d 7.1% 3) 100-250 JCCLS CRM-001d 4.0% Alkaline Phosphatase（ALP） (U/L) : 1) 80-160 JCCLS CRM-001d 4.2% 2) 30-110 JCCLS CRM-001d 4.3% 3) 130-220 JCCLS CRM-001d 4.2% Lactate dehydrogenase（LD） (U/L) : 1) 250-470 JCCLS CRM-001d 3.0% 2) 100-310 JCCLS CRM-001d 3.3% 3) 400-620 JCCLS CRM-001d 2.8% amylase (U/L) : 1) 120-240 JCCLS CRM-001d 3.0% 2) 40-120 JCCLS CRM-001d 3.1% 3) 240-400 JCCLS CRM-001d 2.8% Creatine Kinase (CK) (U/L) : 1) 200-400 JCCLS CRM-001d 2.8% 2) 50-250 JCCLS CRM-001d 2.8% 3) 400-600 JCCLS CRM-001d 2.8%

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	γ -glutamyltransferase (γ-GT) (U/L) : 1) 60-120 JCCLS CRM-001d 3.5% 2) 20-60 JCCLS CRM-001d 4.7% 3) 120-240 JCCLS CRM-001d 3.5% Cholinesterase (ChE) (U/L) : 1) 300-500 JCCLS CRM-002d 2.0% 2) 200-400 JCCLS CRM-002d 2.2% 3) 150-300 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 Category Class (1) Class (2)	B Biological and clinical properties B2 Clinical chemistry B2.5 Electrolytes and Trace elements
・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-002
・Test method	・Test method for each property: Iron： Nitroso-PSAP method、Bathophenanthroline 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

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・Range of property values ・The expanded uncertainties of property values	・Range of property values, Origin CRM, the expanded uncertainties of property values(k=2)

Iron (μg/dL) :	1) 100-160	NIST SRM37	2.0%
		JCCRM 322-7	3.2%
	2) 160-220	NIST SRM37	2.0%
		JCCRM 322-7	3.2%
	3) 40-100	NIST SRM37	2.2%
		JCCRM 322-7	3.4%
Na (mmol/L) :	1) 145-160	JCCRM 321-8	0.8%
	2) 135-145	JCCRM 321-8	0.7%
	3) 120-135	JCCRM 321-8	0.7%
K (mmol/L) :	1) 5.0-7.0	JCCRM 321-8	1.0%
	2) 3.5-5.0	JCCRM 321-8	0.9%
	3) 2.5-3.5	JCCRM 321-8	0.9%
Cl (mmol/L) :	1) 110-125	JCCRM 321-8	0.9%
	2) 100-110	JCCRM 321-8	0.8%
	3) 85-100	JCCRM 321-8	0.9%
Ca (mg/dL) :	1) 9.0-11.0	NIST SRM915b	1.8%
		JCCRM 321-8	1.5%
	2) 7.0-9.0	NIST SRM915b	1.9%
		JCCRM 321-8	1.7%
	3) 5.0-7.5	NIST SRM915b	2.0%
		JCCRM 321-8	2.1%
Inorganic phosphorus (mg/dL) :	1) 6.0-8.0	NIST SRM200b	1.1%
		JCCRM 324-6	2.1%
	2) 4.0-6.0	NIST SRM200b	1.3%
		JCCRM 324-6	2.2%
	3) 2.0-4.0	NIST SRM200b	1.3%
		JCCRM 324-6	2.2%
Mg (mg/dL) :	1) 2.0-3.5	NIST SRM929a	2.4%
		JCCRM 321-8	2.3%
	2) 1.0-2.5	NIST SRM929a	3.2%

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	JCCRM 321-8 3.2% 3) 3.0-5.0 NIST SRM929a 2.1% JCCRM 321-8 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 Category Class (1) Class (2)	B Biological and clinical properties B2 Clinical chemistry 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-002
・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)
・The expanded uncertainties of property values	Glucose（mg/dL）： 1) 50-100 NIST SRM917c 1.4% JCCRM521-14 1.9% 2) 100-150 NIST SRM917c 1.4% JCCRM521-14 1.8% 3) 150-300 NIST SRM917c 1.4% JCCRM521-14 1.8% 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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・Applied Scope of Accreditation Code of Field Category Class (1) Class (2)	・Classification code：B2.7 B Biological and clinical properties B2 Clinical chemistry B2.7 Non-protein Nitrogens
・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-002
・Test method	・Test method for each property: Uric acid：Uricase POD method, Uricase・UV method Urea nitrogen ：Ammonia elimination method, Ammonia avoidance method Creatine ：Enzyme method Total bilirubin ：Vanadic acid oxidation method, Enzyme 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): 1) 7.0-10.0 NIST SRM913b 1.5% JCCRM 521-14 1.6% 2) 5.0-7.0 NIST SRM913b 1.6% JCCRM 521-14 1.6% 3) 2.0-5.0 NIST SRM913b 1.5% JCCRM 521-14 1.7% Urea Nitrogen (mg/dL): 1) 10.0-20.0 NIST SRM912a 2.2% JCCRM 521-14 3.1% 2) 20.0-30.0 NIST SRM912a 2.0% JCCRM 521-14 3.1% 3) 30.0-50.0 NIST SRM912a 2.0% JCCRM 521-14 3.1%

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	Creatine (mg/dL):	1) 0.50-1.00	NIST SRM914a	2.5%
			JCCRM 521-14	3.7%
		2) 1.00-3.00	NIST SRM914a	1.5%
			JCCRM 521-14	3.1%
		3) 3.00-5.00	NIST SRM914a	1.5%
			JCCRM 521-14	3.0%
	Total bilirubin (mg/dL) :	1) 0.5-1.5	NIST SRM916	6.1%
		2) 1.5-3.0	NIST SRM916	5.8%
		3) 3.0-6.0	NIST SRM916	5.4%
	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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