



Reference Material Producer

Accreditation Certificate

Accreditation No. RMP00050



Shimadzu Diagnostics Corporation Yuki plant

1075-2 HOKUNANMORO, YUKI IBARAKI, 307-0036 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	: January 31, 2028

Initial accreditation

January 17, 2024

Y. Iizuka, President

Japan Accreditation Board



Accreditation Certificate Appendix

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Accreditation No. RMP00050

Shimadzu Diagnostics Corporation Yuki plant

Name of reference material producer	Shimadzu Diagnostics Corporation Yuki plant			
Address	Zip	307-0036	Address	1075-2 HOKUNANMORO, YUKI IBARAKI, JAPAN
Applied Scope of Accreditation Code of Field Category Class (1) Class (2)	Code of Field: B2.1 Category : Biological and clinical reference materials Class (1) : Clinical Chemistry Class (2) : Protein			
Type of reference Material	Reference materials			
Name of reference material	Frozen pool serum for quality control L-Suitrol Plus			
Test method	Test method for each item Total protein (TP) Biuret method Albumin (Alb) BCP Improvement Method C-reactive protein (CRP) Latex immunoturbidimetry			
Range of property values	Range of characteristic values, expanded uncertainty ($k=2$) <L-Suitrol Plus 1 > Total protein (TP) (g/dL) : 5.5-6.5 3.3% Albumin (Alb) (g/dL) : 3.3-4.3 4.0% C-reactive protein (CRP) (mg/dL) : 0.3-0.5 4.9% <L-Suitrol Plus 2 > Total protein (TP) (g/dL) : 7.5-8.5 3.6% Albumin (Alb) (g/dL) : 4.3-5.3 4.1% C-reactive protein (CRP) (mg/dL) : 3.7-4.3 4.6%			
The expanded uncertainties of property values	The expanded uncertainty is the calibrated measurement capability (CMC), which correspond to a confidence level of about 95%. Including homogeneity and stability of materials.			



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Accreditation No. RMP00050

Shimadzu Diagnostics Corporation Yuki plant

<ul style="list-style-type: none"> • Applied Scope of Accreditation • Code of Field • Category • Class (1) • Class (2) 	<p>Code of Field : B2.2 Category : Biological and clinical reference materials Class (1) : Clinical Chemistry Class (2) : Lipids and lipoproteins</p>						
<ul style="list-style-type: none"> • Type of reference Material 	<p>Reference materials</p>						
<ul style="list-style-type: none"> • Name of reference material 	<p>Frozen pool serum for quality control L-Suitrol Plus</p>						
<ul style="list-style-type: none"> • Test method 	<p>Test method for each item</p>						
<ul style="list-style-type: none"> • Range of property values 	<table border="0"> <tr> <td>Triglyceride (TG)</td> <td>Enzymatic method (GK-GPO, FG-elimination)</td> </tr> <tr> <td>Total cholesterol (TC)</td> <td>Enzymatic method (COD)</td> </tr> </table>	Triglyceride (TG)	Enzymatic method (GK-GPO, FG-elimination)	Total cholesterol (TC)	Enzymatic method (COD)		
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Total cholesterol (TC)	Enzymatic method (COD)						
<ul style="list-style-type: none"> • The expanded uncertainties of property values 	<p>Range of characteristic values, expanded uncertainty ($k=2$)</p> <p><L-Suitrol Plus 1 ></p> <table border="0"> <tr> <td>Triglyceride (TG) (mg/dL)</td> <td>: 50-150</td> <td>2.1%</td> </tr> <tr> <td>Total cholesterol (TC) (mg/dL)</td> <td>: 100-160</td> <td>2.3%</td> </tr> </table>	Triglyceride (TG) (mg/dL)	: 50-150	2.1%	Total cholesterol (TC) (mg/dL)	: 100-160	2.3%
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	<p><L-Suitrol Plus 2 ></p> <table border="0"> <tr> <td>Triglyceride (TG) (mg/dL)</td> <td>: 150-250</td> <td>2.3%</td> </tr> <tr> <td>Total cholesterol (TC) (mg/dL)</td> <td>: 200-280</td> <td>2.3%</td> </tr> </table>	Triglyceride (TG) (mg/dL)	: 150-250	2.3%	Total cholesterol (TC) (mg/dL)	: 200-280	2.3%
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	<p>The expanded uncertainty is the calibrated measurement capability (CMC), which correspond to a confidence level of about 95%. Including homogeneity and stability of materials.</p>						



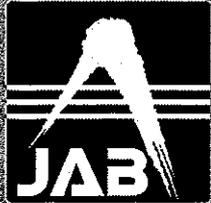
Shimadzu Diagnostics Corporation Yuki plant

Applied Scope of Accreditation	Code of Field : B2.3
Code of Field	Category : Biological and clinical reference materials
Category	Class (1) : Clinical Chemistry
Class (1)	Class (2) : Enzymes
Class (2)	
Type of reference Material	Reference materials
Name of reference material	Frozen pool serum for quality control L-Suitrol Plus
Test method	Test method for each item
Range of property values	Creatine Kinase (CK) JSCC standardized response method
The expanded uncertainties of property values	Aspartic acid Aminotransferase (AST) JSCC standardized response method
	Alanine Aminotransferase (ALT) JSCC standardized response method
	Lactate dehydrogenase (LD) IFCC standardized response method
	Alkaline phosphatase (ALP) IFCC standardized response method
	Gamma-glutamyltransferase (GGT) JSCC standardized response method
	Cholinesterase (ChE) JSCC standardized response method (p-HBC substrate)
	Amylase (AMY) JSCC standardized response method (G7 substrate)
	Range of characteristic values, expanded uncertainty ($k=2$)
	<L-Suitrol Plus 1 >
	Creatine Kinase (CK) (U/L) : 120-240 2.8%
	Aspartic acid Aminotransferase (AST) (U/L) : 20-40 3.4%
	Alanine Aminotransferase (ALT) (U/L) : 25-45 3.4%
	Lactate dehydrogenase (LD) (U/L) : 120-220 4.0%
	Alkaline phosphatase (ALP) (U/L) : 40-90 4.8%
	Gamma-glutamyltransferase (GGT) (U/L) : 30-50 3.5%
	Cholinesterase (ChE) (U/L) : - *1 2.7%
	Amylase (AMY) (U/L) : 60-100 3.3%
	<L-Suitrol Plus 2 >
	Creatine Kinase (CK) (U/L) : 350-550 2.6%
	Aspartic acid Aminotransferase (AST) (U/L) : 100-200 2.8%
	Alanine Aminotransferase (ALT) (U/L) : 110-230 3.1%
	Lactate dehydrogenase (LD) (U/L) : 300-540 3.5%
	Alkaline phosphatase (ALP) (U/L) : 110-200 5.2%
	Gamma-glutamyltransferase (GGT) (U/L) : 100-180 3.4%
	Cholinesterase (ChE) (U/L) : - *1 2.7%
	Amylase (AMY) (U/L) : 250-350 3.1%
	*1 The cholinesterase characteristic value was not set because it depends on the raw material human serum.
	The expanded uncertainty is the calibrated measurement capability (CMC), which correspond to a confidence level of about 95%. Including homogeneity and stability of materials.



Shimadzu Diagnostics Corporation Yuki plant

<ul style="list-style-type: none"> • Applied Scope of Accreditation • Code of Field • Category • Class (1) • Class (2) 	<p>Code of Field : B2.5 Category : Biological and clinical reference materials Class (1) : Clinical Chemistry Class (2) : Electrolytes and trace elements</p>																																																
<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>Reference materials Frozen pool serum for quality control L-Suitrol Plus</p> <p>Test method for each item</p> <table border="0"> <tr> <td>Sodium (Na)</td> <td>Ion selective electrode dilution method (Hitachi)</td> </tr> <tr> <td>Potassium (K)</td> <td>Ion selective electrode dilution method (Hitachi)</td> </tr> <tr> <td>Chlorine (Cl)</td> <td>Ion selective electrode dilution method (Hitachi)</td> </tr> <tr> <td>Magnesium (Mg)</td> <td>Enzymatic method (ICDH)</td> </tr> <tr> <td>Calcium (Ca)</td> <td>Enzymatic method (PLD)</td> </tr> <tr> <td>Inorganic phosphorus (IP)</td> <td>Enzymatic method (PNP)</td> </tr> <tr> <td>Iron (Fe)</td> <td>Direct method (Nitroso-PSAP)</td> </tr> </table>	Sodium (Na)	Ion selective electrode dilution method (Hitachi)	Potassium (K)	Ion selective electrode dilution method (Hitachi)	Chlorine (Cl)	Ion selective electrode dilution method (Hitachi)	Magnesium (Mg)	Enzymatic method (ICDH)	Calcium (Ca)	Enzymatic method (PLD)	Inorganic phosphorus (IP)	Enzymatic method (PNP)	Iron (Fe)	Direct method (Nitroso-PSAP)																																		
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Shimadzu Diagnostics Corporation Yuki plant

<ul style="list-style-type: none"> • Applied Scope of Accreditation • Code of Field • Category • Class (1) • Class (2) 	<p>Code of Field : B2.6 Category : Biological and clinical reference materials Class (1) : Clinical Chemistry Class (2) : Carbohydrates</p> <p>Reference materials Frozen pool serum for quality control L-Suitrol Plus</p> <p>Test method for each item Glucose (Glu) Enzymatic method (HK)</p> <p>Range of characteristic values, expanded uncertainty ($k=2$)</p> <table border="0"> <tr> <td colspan="3"><L-Suitrol Plus 1 ></td> </tr> <tr> <td>Glucose (Glu) (mg/dL)</td> <td>: 85-105</td> <td>2.1%</td> </tr> <tr> <td colspan="3"><L-Suitrol Plus 2 ></td> </tr> <tr> <td>Glucose (Glu) (mg/dL)</td> <td>: 280-320</td> <td>2.0%</td> </tr> </table> <p>The expanded uncertainty is the calibrated measurement capability (CMC), which correspond to a confidence level of about 95%. Including homogeneity and stability of materials.</p>	<L-Suitrol Plus 1 >			Glucose (Glu) (mg/dL)	: 85-105	2.1%	<L-Suitrol Plus 2 >			Glucose (Glu) (mg/dL)	: 280-320	2.0%
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Shimadzu Diagnostics Corporation Yuki plant

<ul style="list-style-type: none"> • Applied Scope of Accreditation • Code of Field • Category • Class (1) • Class (2) 	<p>Code of Field : B2.7 Category : Biological and clinical reference materials Class (1) : Clinical Chemistry Class (2) : Non-protein nitrogen compounds</p>																								
<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>Reference materials Frozen pool serum for quality control L-Suitrol Plus</p> <p>Test method for each item Creatinine (Cre) Enzymatic method Uric acid (UA) Enzymatic method (Uricase, POD) Urea nitrogen (UN) Enzymatic method (Urease, GLDH)</p> <p>Range of characteristic values, expanded uncertainty ($k=2$)</p> <table border="0"> <tr> <td colspan="3"><L-Suitrol Plus 1 ></td> </tr> <tr> <td>Creatinine (Cre) (mg/dL)</td> <td>: 0.8-1.2</td> <td>3.7%</td> </tr> <tr> <td>Uric acid (UA) (mg/dL)</td> <td>: 3.0-4.4</td> <td>2.6%</td> </tr> <tr> <td>Urea nitrogen (UN) (mg/dL)</td> <td>: 12-19</td> <td>3.1%</td> </tr> <tr> <td colspan="3"><L-Suitrol Plus 2 ></td> </tr> <tr> <td>Creatinine (Cre) (mg/dL)</td> <td>: 5.0-7.0</td> <td>2.7%</td> </tr> <tr> <td>Uric acid (UA) (mg/dL)</td> <td>: 9.0-11.0</td> <td>1.8%</td> </tr> <tr> <td>Urea nitrogen (UN) (mg/dL)</td> <td>: 45-55</td> <td>2.3%</td> </tr> </table> <p>The expanded uncertainty is the calibrated measurement capability (CMC), which correspond to a confidence level of about 95%. Including homogeneity and stability of materials.</p>	<L-Suitrol Plus 1 >			Creatinine (Cre) (mg/dL)	: 0.8-1.2	3.7%	Uric acid (UA) (mg/dL)	: 3.0-4.4	2.6%	Urea nitrogen (UN) (mg/dL)	: 12-19	3.1%	<L-Suitrol Plus 2 >			Creatinine (Cre) (mg/dL)	: 5.0-7.0	2.7%	Uric acid (UA) (mg/dL)	: 9.0-11.0	1.8%	Urea nitrogen (UN) (mg/dL)	: 45-55	2.3%
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