

ReCCS Reference Materials

(Reference Material Institute for Clinical Chemistry Standards (ReCCS))

○ CRM for Measurement of HbA1c

- CRM for Measurement of HbA1c cutoff value test : JCCRM 400-1

Lot No.	HbA1c (NGSP) values (%)
JCCRM 400-1 cutoff level	6.5 ± 0.1
JCCRM 400-1 H	10.5 ± 0.2

- CRM for Measurement of HbA1c : JCCRM 411-4

· HbA1C (NGSP)

	HbA1c (NGSP) (%)	Expanded Uncertainty (%)
Level 1	5.08	0.20
Level 2	5.80	0.16
Level 3	7.43	0.17
Level 4	9.58	0.21
Level 5	12.02	0.29

· HbA1c (IFCC)

	HbA1c (IFCC) (mmol/mol)	Expanded Uncertainty (mmol/mol)
Level 1	30.5	1.0
Level 2	37.2	1.9
Level 3	53.9	2.3
Level 4	76.7	2.4
Level 5	102.5	3.5

- CRM for Measurement of HbA1c : JCCRM 423-10b

Lot No.	HbA1c (NGSP) values (%)
JCCRM 423-10b M	5.59 ± 0.14
JCCRM 423-10b H	7.70 ± 0.19
JCCRM 423-10b HH	10.57 ± 0.25

○ **CRM for Measurement of Lipid**

- CRM for Measurement of Total Cholesterol and Glycerides in Human Serum :

JCCRM 211-7

Levels	Total Cholesterol
JCCRM 211-7 (TC/M)	4.764 ± 0.039 mmol/L (184.2 ± 1.5 mg/dL)
JCCRM 211-7 (TC/H)	6.210 ± 0.052 mmol/L (240.1 ± 2.0 mg/dL)

Levels	Total Glycerides	Free Glycerol
JCCRM 211-7 (TC/M, FG)	1.512 ± 0.020 mmol/L (133.9 ± 1.7 mg/dL)	0.051 ± 0.003 mmol/L (4.5 ± 0.3mg/dL)
JCCRM 211-7 (TC/H, FG)	2.066 ± 0.027mmol/L (182.9 ± 2.4mg/dL)	0.037 ± 0.003 mmol/L (3.3 ± 0.2 mg/dL)

- CRM for Measurement of Total cholesterol, HDL Cholesterol ,LDL Cholesterol, Triglycerides and Total glycerides in Human Serum :

JCCRM 223-46

Unit: mg/ dL (mmol/L)(25°C)

	Total Cholesterol (Abell-Kendall method)		HDL Cholesterol (CDC reference Method- Abell-Kendall method)		Triglycerides (ID-GC/MS method)		LDL Cholesterol (CDC reference Method- Abell-Kendall method)	
	Certified value	Uncertainty	Certified value	Uncertainty	Certified value	Uncertainty	Certified value	Uncertainty
JCCRM 223-46 ①	140.04 (3.631)	1.8 (0.047)			-			
JCCRM 223-46 ②	172.0 (4.450)	2.3 (0.060)			116.7 (1.318)	2.3 (0.026)		
JCCRM 223-46 ③	199.5 (5.161)	2.7 (0.071)						
JCCRM 223-46 ④			48.1 (1.244)	1.4 (0.036)				
JCCRM 223-46 ⑤			61.7 (1.595)	1.7 (0.043)				
JCCRM 223-46 ⑥					172.7 (1.950)	3.4 (0.039)		
JCCRM 223-46 ⑦							100.4 (2.598)	1.9 (0.049)
JCCRM 223-46 ⑧							129.0 (3.336)	2.0 (0.052)

- CRM for Measurement of HDL-cholesterol, LDL-cholesterol and Triglycerides in Human Serum: JCCRM 224-16

Table 1a. Certified Mass Concentration Values for HDL-C and LDL-C

Unit: mg/dL

Item	HDL-C		LDL-C	
	Certified value	Uncertainty	Certified value	Uncertainty
JCCRM 224-16 (I)	47.9	0.7	-	
JCCRM 224-16 (II)	-		100.4	1.9

Table 1b. Certified Amount-of-Substance Concentration Values for HDL-C and LDL-C

Unit: mmol/L

Item	HDL-C		LDL-C	
	Certified value	Uncertainty	Certified value	Uncertainty
JCCRM 224-16 (I)	1.239	0.018	-	
JCCRM 224-16 (II)	-		2.597	0.049

Table 2a: Certified Mass Concentration Value for Triglycerides

Unit : mg/dL

Item	Triglycerides	
	Certified value	Uncertainty
JCCRM 224-16 (III)	131.9	1.6

Table2b: Certified A mount of S ubstance C oncentration Value for Triglycerides

Unit : mmol/L

Item	Triglycerides	
	Certified value	Uncertainty
JCCRM 224-16 (III)	1.489	0.018

○ CRM for Electrolytes in Human Serum, Blood Gases, ISE, Dialysate

- CRM for Ion Selective Electrode(ISE) : JCCRM 111-9

(unit: mmol/L,25°C)

Item	JCCRM111-9L Low Level	JCCRM111-9M Medium Level	JCCRM111-9H High Level
Na (Sodium)	128.7±0.3	142.1±0.3	158.7±0.4
K(potassium)	3.276±0.015	4.274±0.017	5.589±0.021
Cl(chloride)	91.3±0.4	105.8±0.5	123.7±0.5

- CRM for dialysate measurement : JCCRM 300-16

Table 1: Acetic acid component: JCCRM 300A-16

Type	JCCRM 300A-16M (Medium concentration)		JCCRM 300A-16H (High concentration)		Unit
	Certified value	Expanded uncertainty	Certified value	Expanded uncertainty	
pH	7.26	0.04	-	-	-(37°C)
pCO ₂	67.1	1.6	-	-	mmHg (37°C)
	8.9	0.2	-	-	kPa (37°C)
HCO ₃	28.5	0.7	-	-	mmol/L (37°C)
Na	140.0	0.5	160.0	0.6	mmol/L
K	1.96	0.01	3.97	0.02	mmol/L
Cl	109.6	0.5	131.7	0.5	mmol/L

(Measured at 37°C for pH, pCO₂, and HCO₃⁻. Measured at 25°C for Na, K and Cl)

Table 2: Citric acid component: JCCRM 300C-16

Type	JCCRM 300C-16M (Medium concentration)		JCCRM 300C-16H (High concentration)		Unit
	Certified value	Expanded uncertainty	Certified value	Expanded uncertainty	
pH	7.60	0.04	-	-	-(37°C)
pCO ₂	34.3	1.0			mmHg(37°C)
	4.6	0.1			kPa(37°C)
HCO ₃	32.5	1.0			mmol/L (37)
Na	139.6	0.6	159.2	0.7	mmol/L
K	1.96	0.01	3.96	0.02	mmol/L
Cl	111.5	0.5	133.3	0.5	mmol/L

(Measured at 37°C for HCO₃⁻. Measured at 25°C for Na, K and Cl)

- CRM for Measurements of Electrolytes in Human Serum : JCCRM 321-8

The values below are at 25°C

Item	JCCRM321-8L Low Level	JCCRM321-8M Medium Level	JCCRM321-8H High Level	Unit
Na	124.3 ± 0.6	140.3 ± 0.6	157.7 ± 0.7	mmol/L
K	3.42 ± 0.02	4.18 ± 0.03	5.52 ± 0.03	mmol/L
Cl	88.0 ± 0.5	104.5 ± 0.6	125.2 ± 0.6	mmol/L
Total Ca	-	10.4 ± 0.11 (2.58 ± 0.03)	12.4 ± 0.13 (3.10 ± 0.03)	mg/dL (mmol/L)
Total Mg	-	2.03 ± 0.02 (0.84 ± 0.01)	2.98 ± 0.03 (1.23 ± 0.01)	mg/dL (mmol/L)
IP	-	3.5 ± 0.1	-	mg/dL

- CRM for Measurement of Serum Iron : JCCRM 322-7

The certified values and expanded uncertainties of this CRM are as follows (25°C)

Item	Low concentration JCCRM 322-7L	Medium concentration JCCRM 322-7M	Unit
Serum iron	36.6 ± 1.1	133.6 ± 3.6	µg/dL
	6.6 ± 0.2	23.9 ± 0.6	µmol/L

- CRM for Blood Gas : JCCRM 621-4

Table 1: Gas equilibration temperature for the reference material: 37°C

Item	Certified values & Expanded uncertainties			Unit
	Level 1	Level 2	Level 3	
pH	7.339 ± 0.022	7.445 ± 0.023	7.546 ± 0.022	-
pCO2	54.5 ± 1.3	38.5 ± 1.4	27.3 ± 1.1	mmHg
pO2	40.6 ± 1.4	61.7 ± 2.0	81.4 ± 3.0	mmHg

Measured temperature : 37°C

Table 2: Gas equilibration temperature for the reference material: 30° C

Item	Certified values & Expanded uncertainties			Unit
	Level 1	Level 2	Level 3	
pH	7.299 ± 0.023	7.414 ± 0.024	7.526 ± 0.023	-
pCO2	61.3 ± 1.9	41.9 ± 1.7	29.4 ± 1.2	mmHg
pO2	47.0 ± 1.1	79.3 ± 2.7	105.1 ± 2.5	mmHg

Measured temperature: 37°C

- CRM for Ion Selective Electrode : JCTCM 130-3

mmol/L (25°C)

Item	JCCRM130-3L Low concentration	JCCRM130-3M Medium concentration	JCCRM130-3H High concentration
Sodium	125.3 ± 0.6	140.7 ± 0.7	154.2 ± 0.6
potassium	3.43 ± 0.03	4.38 ± 0.03	5.41 ± 0.03
chloride	89.0 ± 0.5	104.3 ± 0.6	118.6 ± 0.6

- Trueness Control Material for Ion Selective Electrode: JCTCM 131-2

(mmol/L)

	sodium	potassium	chloride
JCTCM 131-2M Medium concentration	141.8 ± 0.6	4.45 ± 0.03	103.0 ± 0.6

○ **CRM for Measurement of Nitrogen-containing, Glucose**

- CRM of Glucose, Creatinine, Uric Acid and Urea Nitrogen in Human Serum:

JCCRM 521-14

• Table1: Certified Concentration Values for Creatinine

	JCCRM 521-14M Medium Level	JCCRM 521-14H High Level	JCCRM 521-14HH Abnormally high Level	unit
Creatinine	0.95 ± 0.03	2.24 ± 0.06	5.27 ± 0.13	mg/dL
	84 ± 3	198 ± 5	466 ± 11	μ mol/L

• Table2: Certified Concentration Values for Uric acid, Urea-Nitrogen and Glucose

	JCCRM 521-14M Medium Level	JCCRM 521-14H High Level	JCCRM 521-14HH Abnormally high Level	unit
Uric acid	5.58 ± 0.08	8.09 ± 0.10	11.82 ± 0.15	mg/dL
	332 ± 5	481 ± 6	703 ± 9	μ mol/L
Urea-Nitrogen	13.7 ± 0.3	28.5 ± 0.7	45.5 ± 0.8	mg/dL
	4.9 ± 0.1	10.2 ± 0.2	16.2 ± 0.3	mmol/L
Glucose	105.7 ± 1.4	151.5 ± 2.0	244.8 ± 3.1	mg/dL
	5.87 ± 0.08	8.41 ± 0.08	13.59 ± 0.18	mmol/L

- CRM for Measurement of Glucose : JCCRM 523-2

Unit: mg/dL (25°C)

	JCCRM 523-2L Low Level	JCCRM 523-2M Medium Level	JCCRM 523-2H High Level
Glucose	75.10 ± 1.0	105.3 ± 1.4	203.7 ± 2.7

○ **CRM for Total Hemoglobin Measurement**

- CRM for Total Hemoglobin Measurement : JCCRM 912-3

(25°C)

	JCCRM 912-3L Low Level	JCCRM 912-3M Medium Level	JCCRM 913-3H High Level	unit
Glucose	8.02 ± 0.12	13.64 ± 0.19	18.59 ± 0.27	g/dL
	80.2 ± 1.2	136.4 ± 1.9	185.9 ± 2.7	g/L

○ **CRM for Measurement of Plasma protein in Human serum**

- CRM for Measurements of Glycated Albumin in Human Serum : JCCRM 611-1

Certified GA(mmol/mol)concentrations

	JCCRM 611-1M	JCCRM 611-1H	JCCRM 611-1HH	unit
Glycated Albumin	230 ± 7	365 ± 10	564 ± 18	mmol/mol

- CRM for Measurement of C-Reactive Protein (CRP) in Human Serum : JCRM 612-1

• Table 1a: Certified Mass Concentration Values and Uncertainty

Unit : mg/dL

Level	0	1	2	3	4
C-Reactive Protein	0.000	0.093 ± 0.005	0.278 ± 0.015	0.921 ± 0.049	4.625 ± 0.243

• Table 1b: Certified Amount of Substance Concentration Values and Uncertainty

Unit : µmol/L

Level	0	1	2	3	4
C-Reactive Protein	0.000	0.040 ± 0.002	0.121 ± 0.007	0.400 ± 0.021	2.009 ± 0.106

- CRM for Measurement of Albumin in Human Serum : JCCRM 613-2

	JCCRM 613-2L	JCCRM 613-2M	unit
Albumin	2.98 ± 0.10	4.30 ± 0.15	mg/dL

○ **CRM for Measurement of Plasma protein in Human serum**

- CRM for Measurement of Uric Acid in Human Serum : JCCRM 811-1

	JCCRM 811-1M (Medium Concentration)	JCCRM 811-1H (High Concentration)	JCCRM 811-1HH (Abnormally high area)	unit
Uric acid	4.342 ± 0.010	7.496 ± 0.017	10.715 ± 0.028	mg/dl
	0.2583 ± 0.0006	0.4460 ± 0.0010	0.6374 ± 0.0014	mmol/l

○ Standard Solution

- Standard Solutions for Measurement for GA : JCCRM 614-1

- Table 1 Certified Concentration Values

	Lebel 1	Lebel 2	Lebel 3	Lebel 4	Lebel 5	unit
Lysine	8677 ± 209	9919 ± 239	10924 ± 263	11469 ± 276	10746 ± 258	nmol/g
DOF-Lysine	23.4 ± 0.6	44.1 ± 1.1	66.8 ± 1.7	80.7 ± 2.0	87.5 ± 2.2	nmol/g

- Table 2 Concentration Values

		unit
d ₄ -Ltsube	11000	nmol/g
¹³ C ₆ -DOF-Lysine	45	nmol/g

○ **RM for Human Multi-Enzymes(ERM), Reference Standard(ChE) certified by JCCLS**

- Human multi enzymes reference material : JCCLS CRM-001d

(37°C)

	Certified values (U/L)	Uncertainties (U/L)
AST	160	±4
ALT	158	±4
CK	425	±10
ALP	424	±13
LD	406	±8
γ-GT	153	±5
AMY	344	±9
IFCC-ALP	153	±6
IFCC-LD	430	±11

- Reference Standard ChE : JCCLS CRM-002d

(37°C)

	Certified values (U/L)	Uncertainties (U/L)
cholinesterase	539	±9