MEASURE Human Lyo L-2
for MESURE Reagent

Lot. 217AFB (Blue Cap)

2℃～8℃ EXP. 2027.08.

Manufacture Date : 2026.02.02.

Component	Analytical value		1SD	Acceptable range			Method/Instrument	Traceability
Albumin	**55.8**	**g/L**	**1.86**	**50.2**	-	**61.4**	**BCG / Hitachi-7180**	JCCRM613
	5.58	g/dL	0.186	5.02	-	6.14	±3SD range by MEASURE Reagent	(ERM DA470)
ALT	**142**	**U/L**	**4.73**	**128**	-	**156**	**JSCC at 37°C (IFCC w/o PalP) / Hitachi-7180**	JCCRM001d
	2.37	μkat/L	0.079	2.13	-	2.61	±3SD range by MEASURE Reagent	
ALP IFCC	**258**	**U/L**	**12.9**	**219**	-	**297**	**IFCC at 37°C / Hitachi-7180**	JCCRM001d (IFCC)
	4.31	μkat/L	0.215	3.66	-	4.95	±3SD range by MEASURE Reagent	
Amylase, total	**378**	**U/L**	**18.90**	**321**	-	**435**	**IFCC at 37°C / Hitachi-7180**	JCCRM001d
	6.31	μkat/L	0.316	5.37	-	7.26	±3SD range by MEASURE Reagent	
AST	**214**	**U/L**	**7.13**	**193**	-	**235**	**JSCC at 37°C (IFCC w/o PalP) / Hitachi-7180**	JCCRM001d
	3.57	μkat/L	0.119	3.22	-	3.93	±3SD range by MEASURE Reagent	
Bilirubin, direct	**39.8**	**μmol/L**	**2.656**	**31.9**	-	**47.8**	**Enzymatic / Hitachi-7180**	NIST
	2.33	mg/dL	0.132	1.86	-	2.80	±3SD range by MEASURE Reagent	
Bilirubin, total	**72.5**	**μmol/L**	**2.42**	**65.3**	-	**79.8**	**Enzymatic / Hitachi-7180**	NIST
	4.24	mg/dL	0.141	3.82	-	4.66	±3SD range by MEASURE Reagent	
Cholesterol, total	**5.85**	**mmol/L**	**0.195**	**5.27**	-	**6.44**	**CHOD-PAP / Hitachi-7180**	JCCRM223
	226	mg/dL	7.5	203	-	249	±3SD range by MEASURE Reagent	(SRM1951a)
HDL Cholesterol (*)	**1.86**	**mmol/L**	**0.124**	**1.49**	-	**2.24**	**Direct enzymatic colorimetry / Hitachi-7180**	JCCRM223
	72.0	mg/dL	4.80	57.6	-	86.4	±3SD range by MEASURE Reagent	(SRM1951a)
LDL Cholesterol	**3.78**	**mmol/L**	**0.189**	**3.21**	-	**4.35**	**Direct enzymatic colorimetry / Hitachi7180**	JCCRM223
	146	mg/dL	7.30	124	-	168	±3SD range by MEASURE Reagent	(SRM1951a)
CK	**306**	**U/L**	**15.30**	**260**	-	**352**	**JSCC at 37°C / Hitachi-7180**	JCCRM001d
	5.11	μkat/L	0.256	4.34	-	5.88	±3SD range by MEASURE Reagent	
CK-MB	**69.0**	**U/L**	**9.20**	**41.4**	-	**96.6**	**Immunological UV / Hitachi-7180**	Internal SOP
	1.15	μkat/L	0.154	0.69	-	1.61	±3SD range by MEASURE Reagent	
Creatinine	**240**	**μmol/L**	**9.62**	**212**	-	**269**	**Enzymatic / Hitachi-7180**	JCCRM521
	2.72	mg/dL	0.109	2.39	-	3.05	±3SD range by MEASURE Reagent	(ID-MS)
GGT	**154**	**U/L**	**6.16**	**136**	-	**172**	**JSCC at 37°C / Hitachi-7180**	JCCRM001d
	2.57	μkat/L	0.309	2.26	-	2.88	±3SD range by MEASURE Reagent	
Glucose	**10.2**	**mmol/L**	**0.340**	**9.19**	-	11.2	**HK/G6P-DH / Hitachi-7180** **HDAOS-POD / Hitachi-7180**	JCCRM521
	184	mg/dL	6.13	166	-	202	±3SD range by MEASURE Reagent	(ID-MS/SRM917)
LDH IFCC	**329**	**U/L**	**11.0**	**296**	-	**362**	**IFCC at 37°C / Hitachi-7180**	JCCRM001d
	5.49	μkat/L	0.183	4.94	-	6.04	±3SD range by MEASURE Reagent	
Protein,total	**89.5**	**g/L**	**2.98**	**80.6**	-	**98**	**Modified Biuret / Hitachi-7180**	JCCRM613
	8.95	g/dL	0.298	8.06	-	9.8	±3SD range by MEASURE Reagent	(srm927)
Trglyceride	**1.00**	**mmol/L**	**0.033**	**0.90**	-	**1.10**	**GPO/PAP**	JCCRM223
	87.6	mg/dL	2.92	78.8	-	96	±3SD range by MEASURE Reagent	(ID-MS)
(TG-T)	**4.63**	**mmol/L**	**0.154**	**4.17**	-	**5.09**	**GPO/PAP**	JCCRM223
	406	mg/dL	13.53	365	-	447	±3SD range by MEASURE Reagent	(ID-MS)
Urea Nitrogen	**13.4**	**mmol/L**	**0.446**	**12.1**	-	**14.7**	**Urease-UV / Hitachi-7180**	JCCRM521
	37.4	mg/dL	1.25	33.7	-	41.1	±3SD range by MEASURE Reagent	(id-ms/srm912)
Uric acid	**696**	**μmol/L**	**23.2**	**627**	-	**766**	**Uricase-POD / Hitachi-7180**	JCCRM521
	11.7	mg/dL	0.390	10.5	-	12.9	±3SD range by MEASURE Reagent	(ID-MS)

Acceptable range : ± 3SD

HDL Cholesyerol value is Provisional value

LDH, ALP : As the method has already been switched to IFCC, it has been removed from this lot.

Glucose : Added values using the HK/G6P-DH method

Tester	Quality Control Manager	Manufacturing Control Manager
吉海	吉海	横瀬

UMA Co,.Ltd.

MEASURE Human Lyo L-2

(Other Method)

Lot. 217AFB (Blue Cap)

2°C ~ 8°C EXP. 2027.08. Manufacture Date : 2026.02.02.

Component	Analytical value		U	Acceptable range	Method/Instrument	Traceability
ALT	158	U/L	17	141 - 175	IFCC 37°C with PalP	IFCC
	2.64	µkat/L	0.28	2.35 - 2.92		
Albumin	55.8	g/L	4.8	51.0 - 60.6	BCG	CRM470
	5.58	g/dL	0.38	5.20 - 5.96		
ALP	287	U/L	27	260 - 314	IFCC at 37°C	IFCC
	4.79	µkat/L	0.45	4.34 - 5.24		
Amylase, total	360	U/L	25	335 - 385	IFCC at 37°C	IFCC
	6.01	µkat/L	0.42	5.59 - 6.43		
Amylase, pancreas	186	U/L	15	171 - 201	Enzymatic colorimetry 37°C	
	3.11	µkat/L	0.25	2.86 - 3.36		
AST	230	U/L	20	210 - 250	IFCC 37°C with PalP	IFCC
	3.84	µkat/L	0.33	3.51 - 4.18		
Bilirubin, direct	15.6	µmol/L	1.6	14.0 - 17.2	Diazo	
	0.91	mg/dL	0.09	0.82 - 1.01		
Bilirubin, total	66.6	µmol/L	8.1	58.5 - 74.7	DPD	Doumas method
	3.89	mg/dL	0.47	3.42 - 4.37		
Calucium	3.07	mmol/L	0.15	2.92 - 3.22	NM-BAPTA	SRM909b
	12.3	mg/dL	0.60	11.70 - 12.91		
Chloride	126	mmol/L	6	120 - 132	Indirect ISE	Gravimetry
Cholesterol, total	5.72	mmol/L	0.47	5.25 - 6.19	CHOD/PAP	ID-MS
	221	mg/dL	18	203 - 239		
HDL Cholesterol	1.54	mmol/L	0.22	1.32 - 1.76	Direct enzymatic colorimetry	SRM1951a
	59.6	mg/dL	9	51.0 - 68.1		
LDL Cholesterol	3.27	mmol/L	0.34	2.93 - 3.61	Direct enzymatic colorimetry	SRM1951a
	126	mg/dL	13	113 - 140		
CK	341	U/L	44	297 - 385	IFCC at 37°C	IFCC
	5.69	µkat/L	0.73	4.96 - 6.43		
CK-MB	53.0	U/L	13	40.0 - 66.0	Immunological UV	ERM-AD455/IFCC
	0.89	µkat/L	0.22	0.67 - 1.10		
Copper	30.1	µmol/L	3	27.1 - 33.1	ICP-MS	SRM 3114
Creatinine	252	µmol/L	20	232 - 272	Enzymatic colorimetry	ID-MS
	2.85	mg/dL	0.23	2.62 - 3.08		
GGT	152	U/L	10	142 - 162	IFCC at 37°C	IFCC
	2.54	µkat/L	0.17	2.37 - 2.71		
GLDH	8.95	U/L	1.0	7.95 - 10.0	DGKC 37°C	
	0.15	µkat/L	0.02	0.13 - 0.17		
Glucose	10.4	mmol/L	0.9	9.50 - 11.3	HK/G6P-DH	ID-MS
	187	mg/dL	16	171 - 204		
Iron	34.8	µmol/L	2.7	32.1 - 37.5	Ascorbate/FerroZine	SRM937
	194	µg/dL	15.1	179 - 209		
Lactate	6.35	mmol/L	0.4	5.95 - 6.75	LOD/POD	Primery reference material
	57.2	mg/dL	3.6	53.6 - 60.8		
LDH	316	U/L	40	276 - 356	IFCC at 37°C	IFCC
	5.28	µkat/L	0.67	4.61 - 5.95		
Lipase	96.8	U/L	11	85.8 - 108	Enzymatic colorimetry 37°C	Roche reagent manual measurement
	1.62	µkat/L	0.18	1.43 - 1.80		
Lithium	1.93	mmol/L	0.05	1.88 - 1.98	Colorimetry	
	1.34	mg/dL	0.03	1.30 - 1.37		
Magnesium	1.46	mmol/L	0.11	1.35 - 1.57	Xylidyl-blue	Gravimetry
	3.55	mg/dL	0.27	3.28 - 3.82		
Phosphorus	2.88	mmol/L	0.17	2.71 - 3.05	Ammonium phosphomoplybdate	Primary reference material
	8.92	mg/dL	0.53	8.39 - 9.45		
Potassium	5.95	mmol/L	0.34	5.61 - 6.29	Indirect ISE	Gravimetry
Protein total	86.8	g/L	8	78.8 - 95	Biuret	SRM927c
	8.68	g/dL	0.8	7.88 - 9.48		
Sodium	152	mmol/L	6	146 - 158	Indirect ISE	Gravimetry
Theophyline	121	µmol/L			KIMS	Gravimetry
Total Bile Acid	121	µmol/L	21	100 - 142	Enzymatic endpoint	
	47.2	mg/L	8.19	39.0 - 55.4		
Trglyceride	4.47	mmol/L	0.4	4.07 - 4.87	GPO/PAP	ID-MS
	396	mg/dL	35	360 - 431		

MEASURE Human Lyo L-2

(Other Method)

Lot. 217AFB (Blue Cap)

2°C ～ 8°C **EXP. 2027.08.** Manufacture Date : 2026.02.02.

Component	Analytical value		U	Acceptable range	Method/Instrument	Traceability
UIBC	**42.6**	**µmol/L**	**5.8**	**36.8 - 48.4**	**FeroZine®**	**Primary reference material**
	238	µg/dL	32	205 - 270		
Urea	**13.5**	**mmol/L**	**1.2**	**12.3 - 14.7**	**Urease/GLZDH**	**SRM909b**
	37.8	mg/dL	3.4	34.5 - 41.2		
Uric acid	**665**	**µmol/L**	**62**	**603 - 727**	**Uricase/POD**	**ID-MS**
	11.2	mg/dL	1.04	10.1 - 12.2		
Zinc	**36.0**	**µmol/L**	**2.1**	**33.9 - 38.1**	**ICP-MS**	**SRM 3168a**
	235	µg/dL	14	222 - 249		

* (u) : uncertainty Acceptable range : ± 3SD

The following component will be removed from this lot and later, because the manufacturer's assigned values are not available.

Apo-A, Apo-B CHE, Estoradiol, Ferritin, Folate, HBDH, β-HCG, Homocystaine, IgA, IgG, IgM, NEFA, Osmolality, Phospholipids, Progesterone, f-T3,T3,f-T4,T4,Testosteron, Transferrin, TSH.