

**MEASURE Human Lyo L-2****for MEASURE Reagent****Lot. 216ADC****(Blue Cap)**

2°C~8°C

EXP. 2025.09.

Component	Analytical value	1SD	Acceptable range	Method/Instrument	Traceability
Albumin	59.4 g/L	1.98	53.5 - 65.3	BCG / Hitachi-7180	JCCRM613
	5.94 g/dL	0.198	5.35 - 6.53	±3SD range by MEASURE Reagent	(ERM DA470)
ALT	148 U/L	4.93	133 - 163	JSCC at 37°C (IFCC w/o PaIP) / Hitachi-7180	JCCRM001d
	2.47 μkat/L	0.082	2.22 - 2.72	±3SD range by MEASURE Reagent	
ALP	319 U/L	16.0	271 - 367	IFCC at 37°C / Hitachi-7180	JCCRM001d (IFCC)
	5.33 μkat/L	0.267	4.53 - 6.13	±3SD range by MEASURE Reagent	
ALP IFCC	285 U/L	14.3	242 - 328	IFCC at 37°C / Hitachi-7180	JCCRM001d (IFCC)
	4.76 μkat/L	0.238	4.05 - 5.47	±3SD range by MEASURE Reagent	
Amylase, total	382 U/L	19.10	325 - 439	IFCC at 37°C / Hitachi-7180	JCCRM001d
	6.38 μkat/L	0.319	5.42 - 7.34	±3SD range by MEASURE Reagent	
AST	230 U/L	7.67	207 - 253	JSCC at 37°C (IFCC w/o PaIP) / Hitachi-7180	JCCRM001d
	3.84 μkat/L	0.128	3.46 - 4.23	±3SD range by MEASURE Reagent	
Bile Acid	116 μmol/L	11.60	81.2 - 151	Enzymatic (3-α-HDS) / Hitachi-7180	Gravimetry
	45.1 mg/L	4.507	31.5 - 58.6	±3SD range by MEASURE Reagent	
Bilirubin, direct	38.3 μmol/L	2.554	30.6 - 46.0	Enzymatic / Hitachi-7180	NIST
	2.24 mg/dL	0.132	1.79 - 2.69	±3SD range by MEASURE Reagent	
Bilirubin, total	75.4 μmol/L	2.51	67.9 - 83.0	Enzymatic / Hitachi-7180	NIST
	4.41 mg/dL	0.147	3.97 - 4.85	±3SD range by MEASURE Reagent	
Cholesterol, total	6.29 mmol/L	0.210	5.66 - 6.92	CHOD-PAP / Hitachi-7180	JCCRM223
	243 mg/dL	8.1	219 - 267	±3SD range by MEASURE Reagent	(SRM1951a)
HDL Cholesterol <sup>(*)</sup>	2.12 mmol/L	0.141	1.70 - 2.55	Direct enzymatic colorimetry / Hitachi-7180	JCCRM223
	81.9 mg/dL	5.46	65.5 - 98.3	±3SD range by MEASURE Reagent	(SRM1951a)
LDL Cholesterol	3.81 mmol/L	0.190	3.24 - 4.38	Direct enzymatic colorimetry / Hitachi-7180	JCCRM223
	147 mg/dL	7.35	125 - 169	±3SD range by MEASURE Reagent	(SRM1951a)
CK	325 U/L	16.25	276 - 374	JSCC at 37°C / Hitachi-7180	JCCRM001d
	5.43 μkat/L	0.271	4.61 - 6.24	±3SD range by MEASURE Reagent	
CK-MB	74.8 U/L	9.97	44.9 - 104.7	Immunological UV / Hitachi-7180	Internal SOP
	1.25 μkat/L	0.167	0.75 - 1.75	±3SD range by MEASURE Reagent	
Creatinine	272 μmol/L	10.89	240 - 305	Enzymatic / Hitachi-7180	JCCRM521
	3.08 mg/dL	0.123	2.71 - 3.45	±3SD range by MEASURE Reagent	(ID-MS)
GGT	160 U/L	6.40	141 - 179	JSCC at 37°C / Hitachi-7180	JCCRM001d
	2.67 μkat/L	0.321	2.35 - 2.99	±3SD range by MEASURE Reagent	
Glucose	10.5 mmol/L	0.350	9.44 - 11.5	HDAOS-POD / Hitachi-7180	JCCRM521
	189 mg/dL	6.30	170 - 208	±3SD range by MEASURE Reagent	(ID-MS/SRM917)
LDH	334 U/L	11.1	300 - 367	JSCC at 37°C / Hitachi-7180	JCCRM001d
	5.57 μkat/L	0.186	5.02 - 6.13	±3SD range by MEASURE Reagent	
LDH IFCC	344 U/L	11.5	310 - 378	IFCC at 37°C / Hitachi-7180	JCCRM001d
	5.74 μkat/L	0.191	5.17 - 6.32	±3SD range by MEASURE Reagent	
Protein, total	95.2 g/L	3.17	85.7 - 105	Modified Biuret / Hitachi-7180	JCCRM613
	9.52 g/dL	0.317	8.57 - 10.5	±3SD range by MEASURE Reagent	(srn927)
Trglyceride	1.23 mmol/L	0.041	1.11 - 1.35	GPO/PAP	JCCRM223
	108.0 mg/dL	3.60	97.2 - 119	±3SD range by MEASURE Reagent	(ID-MS)
(TG-T)	4.87 mmol/L	0.162	4.38 - 5.35	GPO/PAP	JCCRM223
	427 mg/dL	14.23	384 - 470	±3SD range by MEASURE Reagent	(ID-MS)
Urea Nitrogen	13.3 mmol/L	0.443	12.0 - 14.6	Urease-UV / Hitachi-7180	JCCRM521
	37.1 mg/dL	1.24	33.4 - 40.8	±3SD range by MEASURE Reagent	(id-ms/srm912)
Uric acid	690 μmol/L	23.0	621 - 759	Uricase-POD / Hitachi-7180	JCCRM521
	11.6 mg/dL	0.387	10.4 - 12.8	±3SD range by MEASURE Reagent	(ID-MS)

Acceptable range : ± 3SD

HDL Cholesyerol value is Provisional value

UMA Co.,Ltd.

Tester	Quality Control Manager	Manufacturing Control Manager
		

**MEASURE Human Lyo L-2****( Other Method )****Lot. 216ADC****(Blue Cap)**

2°C ~ 8°C

EXP. 2025.09.

Component	Analytical value		U	Acceptable range		Method/Instrument	Traceability
ALT	155	U/L	17	138	- 172	IFCC 37°C with PaIP	IFCC
	2.59	μkat/L	0.28	2.30	- 2.87		
Albumin	56.7	g/L	4.8	51.9	- 61.5	BCG	CRM470
	5.67	g/dL	0.38	5.29	- 6.05		
ALP	300	U/L	27	273	- 327	IFCC at 37°C	IFCC
	5.01	μkat/L	0.45	4.56	- 5.46		
Amylase, total	372	U/L	25	347	- 397	IFCC at 37°C	IFCC
	6.21	μkat/L	0.42	5.79	- 6.63		
Amylase, pancreas	191	U/L	15	176	- 206	Enzymatic colorimetry 37°C	
	3.19	μkat/L	0.25	2.94	- 3.44		
AST	230	U/L	20	210	- 250	IFCC 37°C with PaIP	IFCC
	3.84	μkat/L	0.33	3.51	- 4.18		
Bilirubin, direct	16.0	μmol/L	1.6	14.4	- 17.6	Diazo	
	0.94	mg/dL	0.09	0.84	- 1.03		
Bilirubin, total	70.2	μmol/L	8.1	62.1	- 78.3	DPD	Doumas method
	4.11	mg/dL	0.47	3.63	- 4.58		
Calucium	3.15	mmol/L	0.15	3.00	- 3.30	NM-BAPTA	SRM909b
	12.6	mg/dL	0.60	12.02	- 13.23		
Chloride	126	mmol/L	6	120	- 132	Indirect ISE	Gravimetry
Cholesterol, total	6.03	mmol/L	0.47	5.56	- 6.50	CHOD/PAP	ID-MS
	233	mg/dL	18	215	- 251		
HDL Cholesterol	1.73	mmol/L	0.22	1.51	- 1.95	Direct enzymatic colorimetry	SRM1951a
	66.9	mg/dL	9	58.4	- 75.4		
LDL Cholesterol	3.45	mmol/L	0.34	3.11	- 3.79	Direct enzymatic colorimetry	SRM1951a
	133	mg/dL	13	120	- 147		
CK	329	U/L	44	285	- 373	IFCC at 37°C	IFCC
	5.49	μkat/L	0.73	4.76	- 6.23		
CK-MB	60.0	U/L	13	47.0	- 73.0	Immunological UV	ERM-AD455/IFCC
	1.00	μkat/L	0.22	0.78	- 1.22		
Copper	30.7	μmol/L	3	27.7	- 33.7	ICP-MS	SRM 3114
Creatinine	255	μmol/L	20	235	- 275	Enzymatic colorimetry	ID-MS
	2.88	mg/dL	0.23	2.66	- 3.11		
GGT	160	U/L	10	150	- 170	IFCC at 37°C	IFCC
	2.67	μkat/L	0.17	2.51	- 2.84		
GLDH	10.3	U/L	1.0	9.30	- 11.3	DGKC 37°C	
	0.17	μkat/L	0.02	0.16	- 0.19		
Glucose	10.6	mmol/L	0.9	9.70	- 11.5	HK/G6P-DH	ID-MS
	191	mg/dL	16	175	- 207		
Iron	37.1	μmol/L	2.7	34.4	- 39.8	Ascorbate/FerroZine	SRM937
	207	μg/dL	15.1	192	- 222		
Lactate	6.03	mmol/L	0.4	5.63	- 6.43	LOD/POD	Primery reference material
	54.3	mg/dL	3.6	50.7	- 57.9		
LDH	329	U/L	40	289	- 369	IFCC at 37°C	IFCC
	5.49	μkat/L	0.67	4.83	- 6.16		
Lipase	97.9	U/L	11	86.9	- 109	Enzymatic colorimetry 37°C	Roche reagent manual measurement
	1.63	μkat/L	0.18	1.45	- 1.82		
Lithium	2.00	mmol/L	0.05	1.95	- 2.05	Colorimetry	
	1.39	mg/dL	0.03	1.35	- 1.42		
Magnesium	1.48	mmol/L	0.11	1.37	- 1.59	Xylidyl-blue	Gravimetry
	3.60	mg/dL	0.27	3.33	- 3.86		
Phosphorus	3.01	mmol/L	0.17	2.84	- 3.18	Ammonium phosphomoplybdate	Primary reference material
	9.32	mg/dL	0.53	8.80	- 9.85		
Potassium	5.97	mmol/L	0.34	5.63	- 6.31	Indirect ISE	Gravimetry SRM927c
Protein total	90.3	g/L	8	82.3	- 98	Biuret	
	9.03	g/dL	0.8	8.23	- 9.83		
Sodium	155	mmol/L	6	149	- 161	Indirect ISE	Gravimetry
Theophylline	127	μmol/L				KIMS	Gravimetry
Total Bile Acid	120	μmol/L	21	99	- 141	Enzymatic endpoint	
	46.8	mg/L	8.19	38.6	- 55.0		
Trglyceride	4.57	mmol/L	0.4	4.17	- 4.97	GPO/PAP	ID-MS
	405	mg/dL	35	369	- 440		

**MEASURE Human Lyo L-2****( Other Method )****Lot. 216ADC****(Blue Cap)****2°C ~ 8°C****EXP. 2025.09.**

Component	Analytical value	U	Acceptable range	Method/Instrument	Traceability
UIBC	45.4 $\mu\text{mol/L}$	5.8	39.6 - 51.2	FeroZine®	Primary reference material
	253 $\mu\text{g/dL}$	32	221 - 286		
Urea	13.0 $\text{mmol/L}$	1.2	11.8 - 14.2	Urease/GLZDH	SRM909b
	36.4 $\text{mg/dL}$	3.4	33.1 - 39.8		
Uric acid	660 $\mu\text{mol/L}$	62	598 - 722	Uricase/POD	ID-MS
	11.1 $\text{mg/dL}$	1.04	10.1 - 12.1		
Zinc	39.7 $\mu\text{mol/L}$	2.1	37.6 - 41.8	ICP-MS	SRM 3168a
	259 $\mu\text{g/dL}$	14	246 - 273		

\* ( u ) : uncertainty      Acceptable range :  $\pm 3\text{SD}$ 

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, Estradiol, Ferritin, Folate, HBDH,  $\beta$ -HCG, Homocysteine, IgA, IgG, IgM, NEFA, Osmolality, Phospholipids, Progesterone, f-T3,T3,f-T4,T4,Testosteron, Transferrin, TSH.