

**MEASURE Human Lyo L-2  
for MESURE Reagent**

**Lot. 216AEF**

**(Blue Cap)**

2°C~8°C EXP. 2026.12.

Manufacture Date : 2025.06.02.

Component	Analytical value	1SD	Acceptable range	Method/Instrument	Traceability
Albumin	59.4 g/L	1.98	53.5 - 65.3	BCG / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM613 (ERM DA470)
	5.94 g/dL	0.198	5.35 - 6.53		
ALT	148 U/L	4.93	133 - 163	JSCC at 37°C (IFCC w/o PaIP) / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
	2.47 µkat/L	0.082	2.22 - 2.72		
ALP	319 U/L	16.0	271 - 367	IFCC at 37°C / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d (IFCC)
	5.33 µkat/L	0.267	4.53 - 6.13		
ALP IFCC	285 U/L	14.3	242 - 328	IFCC at 37°C / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d (IFCC)
	4.76 µkat/L	0.238	4.05 - 5.47		
Amylase, total	382 U/L	19.10	325 - 439	IFCC at 37°C / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
	6.38 µkat/L	0.319	5.42 - 7.34		
AST	230 U/L	7.67	207 - 253	JSCC at 37°C (IFCC w/o PaIP) / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
	3.84 µkat/L	0.128	3.46 - 4.23		
Bile Acid	116 µmol/L	11.60	81.2 - 151	Enzymatic (3-α-HDS) / Hitachi-7180 ±3SD range by MEASURE Reagent	Gravimetry
	45.1 mg/L	4.507	31.5 - 58.6		
Bilirubin, direct	38.3 µmol/L	2.554	30.6 - 46.0	Enzymatic / Hitachi-7180 ±3SD range by MEASURE Reagent	NIST
	2.24 mg/dL	0.132	1.79 - 2.69		
Bilirubin, total	75.4 µmol/L	2.51	67.9 - 83.0	Enzymatic / Hitachi-7180 ±3SD range by MEASURE Reagent	NIST
	4.41 mg/dL	0.147	3.97 - 4.85		
Cholesterol, total	6.29 mmol/L	0.210	5.66 - 6.92	CHOD-PAP / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM223 (SRM1951a)
	243 mg/dL	8.1	219 - 267		
HDL Cholesterol <sup>(*)</sup>	2.12 mmol/L	0.141	1.70 - 2.55	Direct enzymatic colorimetry / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM223 (SRM1951a)
	81.9 mg/dL	5.46	65.5 - 98.3		
LDL Cholesterol	3.81 mmol/L	0.190	3.24 - 4.38	Direct enzymatic colorimetry / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM223 (SRM1951a)
	147 mg/dL	7.35	125 - 169		
CK	325 U/L	16.25	276 - 374	JSCC at 37°C / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
	5.43 µkat/L	0.271	4.61 - 6.24		
CK-MB	74.8 U/L	9.97	44.9 - 104.7	Immunological UV / Hitachi-7180 ±3SD range by MEASURE Reagent	Internal SOP
	1.25 µkat/L	0.167	0.75 - 1.75		
Creatinine	272 µmol/L	10.89	240 - 305	Enzymatic / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM521 (ID-MS)
	3.08 mg/dL	0.123	2.71 - 3.45		
GGT	160 U/L	6.40	141 - 179	JSCC at 37°C / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
	2.67 µkat/L	0.321	2.35 - 2.99		
Glucose	10.5 mmol/L	0.350	9.44 - 11.5	HDAOS-POD / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM521 (ID-MS/SRM917)
	189 mg/dL	6.30	170 - 208		
LDH	334 U/L	11.1	300 - 367	JSCC at 37°C / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
	5.57 µkat/L	0.186	5.02 - 6.13		
LDH IFCC	344 U/L	11.5	310 - 378	IFCC at 37°C / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
	5.74 µkat/L	0.191	5.17 - 6.32		
Protein, total	95.2 g/L	3.17	85.7 - 105	Modified Biuret / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM613 (srm927)
	9.52 g/dL	0.317	8.57 - 10.5		
Trglyceride	1.23 mmol/L	0.041	1.11 - 1.35	GPO/PAP ±3SD range by MEASURE Reagent	JCCRM223 (ID-MS)
	108.0 mg/dL	3.60	97.2 - 119		
(TG-T)	4.87 mmol/L	0.162	4.38 - 5.35	GPO/PAP ±3SD range by MEASURE Reagent	JCCRM223 (ID-MS)
	427 mg/dL	14.23	384 - 470		
Urea Nitrogen	13.3 mmol/L	0.443	12.0 - 14.6	Urease-UV / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM521 (id-ms/srm912)
	37.1 mg/dL	1.24	33.4 - 40.8		
Uric acid	690 µmol/L	23.0	621 - 759	Uricase-POD / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM521 (ID-MS)
	11.6 mg/dL	0.387	10.4 - 12.8		

Acceptable range : ± 3SD

HDL Cholesyerol value is Provisional value

**UMA Co.,Ltd.**

Tester	Quality Control Manager	Manufacturing Control Manager
		

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( Other Method )

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Component	Analytical value	U	Acceptable range	Method/Instrument	Traceability
ALT	155 U/L	17	138 - 172	IFCC 37°C with PalP	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 PalP	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		
Calcium	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	Primary reference material
LDH	54.3 mg/dL	3.6	50.7 - 57.9	IFCC at 37°C	IFCC
	329 U/L	40	289 - 369		
Lipase	5.49 µkat/L	0.67	4.83 - 6.16	Enzymatic colorimetry 37°C	Roche reagent manual measurement
	97.9 U/L	11	86.9 - 109		
Lithium	1.63 µkat/L	0.18	1.45 - 1.82	Colorimetry	
	2.00 mmol/L	0.05	1.95 - 2.05		
Magnesium	1.39 mg/dL	0.03	1.35 - 1.42	Xylidyl-blue	Gravimetry
	1.48 mmol/L	0.11	1.37 - 1.59		
Phosphorus	3.60 mg/dL	0.27	3.33 - 3.86	Ammonium phosphomolybdate	Primary reference material
	3.01 mmol/L	0.17	2.84 - 3.18		
Potassium	9.32 mg/dL	0.53	8.80 - 9.85	Indirect ISE	Gravimetry
	5.97 mmol/L	0.34	5.63 - 6.31		
Protein total	90.3 g/L	8	82.3 - 98	Biuret	SRM927c
	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		

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

\* ( 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.