

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	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 ^(*)	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. 216AEF****(Blue Cap)**

2°C ~ 8°C

EXP. 2026.12.

Manufacture Date : 2025.06.02.

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

MEASURE Human Lyo L-2

(Other Method)

Lot. 216AEF

(Blue Cap)

2°C ~ 8°C

EXP. 2026.12.

Manufacture Date : 2025.06.02.

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.