

MEASURE Human Lyo L-1 for MESURE Reagent

Lot. 117AFB

(White Cap)

2°C~8°C

EXP. 2027.08.

Manufacture Date : 2026.02.02.

Component	Analytical value		1SD	Acceptable range		Method/Instrument	Traceability
Albumin	40.1	g/L	1.34	36.1	- 44.1	BCG / Hitachi-7180	JCCRM613
	4.01	g/dL	0.134	3.61	- 4.41	±3SD range by MEASURE Reagent	(ERM DA470)
ALT	42.0	U/L	1.40	37.8	- 46.2	JSCC at 37°C (IFCC w/o PalP) / Hitachi-7180	JCCRM001d
	0.70	μkat/L	0.023	0.63	- 0.77	±3SD range by MEASURE Reagent	
ALP IFCC	89.0	U/L	4.5	75.7	- 102	IFCC at 37°C / Hitachi-7180	JCCRM001d (IFCC)
	1.49	μkat/L	0.074	1.26	- 1.71	±3SD range by MEASURE Reagent	
Amylase, total	102	U/L	5.10	86.7	- 117	IFCC at 37°C / Hitachi-7180	JCCRM001d
	1.70	μkat/L	0.085	1.45	- 1.96	±3SD range by MEASURE Reagent	
AST	43.0	U/L	1.43	38.7	- 47.3	JSCC at 37°C (IFCC w/o PalP) / Hitachi-7180	JCCRM001d
	0.72	μkat/L	0.024	0.65	- 0.79	±3SD range by MEASURE Reagent	
Bilirubin, direct	8.89	μmol/L	0.741	6.67	- 11.1	Enzymatic / Hitachi-7180	NIST
	0.52	mg/dL	0.043	0.39	- 0.65	±3SD range by MEASURE Reagent	
Bilirubin, total	16.8	μmol/L	0.56	15.1	- 18.4	Enzymatic / Hitachi-7180	NIST
	0.98	mg/dL	0.033	0.88	- 1.08	±3SD range by MEASURE Reagent	
Cholesterol, total	4.35	mmol/L	0.145	3.92	- 4.79	CHOD-PAP / Hitachi-7180	JCCRM223
	168	mg/dL	5.6	151	- 185	±3SD range by MEASURE Reagent	(SRM1951a)
HDL Cholesterol	1.45	mmol/L	0.097	1.16	- 1.74	Direct enzymatic colorimetry / Hitachi-7180	JCCRM223
	56.1	mg/dL	3.74	44.9	- 67.3	±3SD range by MEASURE Reagent	(SRM1951a)
LDL Cholesterol	2.75	mmol/L	0.137	2.33	- 3.16	Direct enzymatic colorimetry / Hitachi-7180	JCCRM223
	106.0	mg/dL	5.30	90.1	- 122	±3SD range by MEASURE Reagent	(SRM1951a)
CK	93.6	U/L	4.68	79.6	- 108	JSCC at 37°C / Hitachi-7180	JCCRM001d
	1.56	μkat/L	0.078	1.33	- 1.80	±3SD range by MEASURE Reagent	
CK-MB	26.9	U/L	3.59	16.1	- 37.7	Immunological UV / Hitachi-7180	Internal SOP
	0.45	μkat/L	0.060	0.27	- 0.63	±3SD range by MEASURE Reagent	
Creatinine	71.6	μmol/L	3.58	60.9	- 82.3	Enzymatic / Hitachi-7180	JCCRM521
	0.81	mg/dL	0.041	0.69	- 0.93	±3SD range by MEASURE Reagent	(ID-MS)
GGT	38.1	U/L	1.52	33.5	- 42.7	JSCC at 37°C / Hitachi-7180	JCCRM001d
	0.64	μkat/L	0.025	0.56	- 0.71	±3SD range by MEASURE Reagent	
Glucose	4.25	mmol/L	0.142	3.82	- 4.67	HK/G6P-DH / Hitachi-7180	JCCRM521
	76.5	mg/dL	2.55	68.9	- 84.2	HDAOS-POD / Hitachi-7180	(ID-MS/SRM917)
LDH IFCC	145	U/L	4.8	131	- 160	IFCC at 37°C / Hitachi-7180	JCCRM001d
	2.42	μkat/L	0.081	2.18	- 2.66	±3SD range by MEASURE Reagent	
Protein, total	63.5	g/L	2.12	57.2	- 69.9	Modified Biuret / Hitachi-7180	JCCRM613
	6.35	g/dL	0.212	5.72	- 6.99	±3SD range by MEASURE Reagent	(srn927)
Trglyceride	0.71	mmol/L	0.024	0.64	- 0.78	GPO/PAP	JCCRM223
	62.1	mg/dL	2.07	55.9	- 68.3	±3SD range by MEASURE Reagent	(ID-MS)
(TG-T)	1.20	mmol/L	0.040	1.08	- 1.32	GPO/PAP	JCCRM223
	105	mg/dL	3.50	94.5	- 116	±3SD range by MEASURE Reagent	(ID-MS)
Urea Nitrogen	4.26	mmol/L	0.142	3.84	- 4.69	Urease-UV / Hitachi-7180	JCCRM521
	11.9	mg/dL	0.40	10.7	- 13.1	±3SD range by MEASURE Reagent	(id-ms/srn912)
Uric acid	293	μmol/L	9.8	264	- 323	Uricase-POD / Hitachi-7180	JCCRM521
	4.93	mg/dL	0.164	4.44	- 5.42	±3SD range by MEASURE Reagent	(ID-MS)

Acceptable range : ± 3SD

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

UMA Co.,Ltd.

Tester	Quality Control Manager	Manufacturing Control Manager

MEASURE Human Lyo L-1*(Other Method)***Lot. 117AFB****(White Cap)****2°C~ 8°C****EXP. 2027.08.**

Manufacture Date : 2026.02.02.

Component	Analytical value		U *	Acceptable range		Method/Instrument	Traceability
ALT	46.0	U/L	4	42.0	- 50.0	IFCC 37°C with PaIP	IFCC
	0.77	μkat/L	0.07	0.70	- 0.84		
Albumin	42.4	g/L	3.8	38.6	- 46.2	BCG	CRM470
	4.24	g/dL	0.38	3.86	- 4.62		
ALP	93.0	U/L	10	83.0	- 103	IFCC at 37°C	IFCC
	1.55	μkat/L	0.17	1.39	- 1.72		
Amylase, total	97.0	U/L	7	90.0	- 104	IFCC at 37°C	IFCC
	1.62	μkat/L	0.12	1.50	- 1.74		
Amylase, pancreas	51.0	U/L	3	48.0	- 54.0	Enzymatic colorimetry 37°C	
	0.85	μkat/L	0.05	0.80	- 0.90		
AST	46.0	U/L	4	42.0	- 50.0	IFCC 37°C with PaIP	IFCC
	0.77	μkat/L	0.07	0.70	- 0.84		
Bilirubin, direct	4.40	μmol/L	0.7	3.70	- 5.10	Diazo	
	0.26	mg/dL	0.04	0.22	- 0.30		
Bilirubin, total	14.4	μmol/L	2.0	12.4	- 16.4	DPD	Doumas method
	0.84	mg/dL	0.12	0.73	- 0.96		
Calucium	2.17	mmol/L	0.15	2.02	- 2.32	NM-BAPTA	SRM909b
	8.70	mg/dL	0.60	8.10	- 9.30		
Chloride	108	mmol/L	5	103	- 113	Indirect ISE	Gravimetry
Cholesterol, total	4.19	mmol/L	0.24	3.95	- 4.43	CHOD/PAP	ID-MS
	162	mg/dL	9	153	- 171		
HDL Cholesterol	1.22	mmol/L	0.22	1.00	- 1.44	Direct enzymatic colorimetry	SRM1951a
	47.2	mg/dL	9	38.7	- 55.7		
LDL Cholesterol	2.36	mmol/L	0.20	2.16	- 2.56	Direct enzymatic colorimetry	SRM1951a
	91.3	mg/dL	8	83.5	- 99.0		
CK	107	U/L	8	99.0	- 115	IFCC at 37°C	IFCC
	1.79	μkat/L	0.13	1.65	- 1.92		
CK-MB	20.0	U/L	5	15.0	- 25.0	Immunological UV	ERM-AD455/IFCC
	0.33	μkat/L	0.08	0.25	- 0.42		
Copper	16.0	μmol/L	1.2	14.8	- 17.2	ICP-MS	SRM 3114
	102	μg/dL	8	94	- 109		
Creatinine	79.5	μmol/L	6	73.5	- 85.5	Enzymatic colorimetry	ID-MS
	0.90	mg/dL	0.07	0.83	- 0.97		
Digoxin	0.919	nmol/L				LIA Access	
GGT	37.0	U/L	3	34.0	- 40.0	IFCC at 37°C	IFCC
	0.62	μkat/L	0.05	0.57	- 0.67		
GLDH	4.70	U/L	0.4	4.30	- 5.10	DGKC 37°C	
	0.08	μkat/L	0.01	0.07	- 0.09		
Glucose	4.42	mmol/L	0.36	4.06	- 4.78	HK/G6P-DH	ID-MS
	79.6	mg/dL	6	73.1	- 86.1		
Iron	18.0	μmol/L	1.4	16.6	- 19.4	Ascorbate/FerroZine	SRM937
	100.5	μg/dL	7.8	92.7	- 108		
Lactate	2.00	mmol/L	0.2	1.80	- 2.20	LOD/POD	Primery reference material
	18.0	mg/dL	1.8	16.2	- 19.8		
LDH	143	U/L	14	129	- 157	IFCC at 37°C	IFCC
	2.39	μkat/L	0.23	2.15	- 2.62		
Lipase	47.0	U/L	5	42.0	- 52.0	Enzymatic colorimetry 37°C	Roche reagent manual measurement
	0.78	μkat/L	0.08	0.70	- 0.87		
Lithium	0.790	mmol/L	0.02	0.77	- 0.81	Colorimetry	
	0.548	mg/dL	0.01	0.53	- 0.56		
Magnesium	0.875	mmol/L	0.03	0.85	- 0.91	Xylidyl-blue	Gravimetry
	2.13	mg/dL	0.07	2.05	- 2.20		
Phosphorus	1.00	mmol/L	0.06	0.94	- 1.06	Ammonium phosphomoplybdate	Primary reference material
	3.10	mg/dL	0.19	2.91	- 3.28		
Potassium	3.88	mmol/L	0.15	3.73	- 4.03	Indirect ISE	Gravimetry
Protein total	62.8	g/L	5.1	57.7	- 67.9	Biuret	SRM927c
	6.28	g/dL	0.51	5.77	- 6.79		
Sodium	136	mmol/L	5	131	- 141	Indirect ISE	Gravimetry
Theophylline	73.8	μmol/L				KIMS	Gravimetry
Total Bile Acid	24.4	μmol/L	4	20.4	- 28.4	Enzymatic endpoint	
	9.52	mg/L	1.56	7.96	- 11.1		

Component	Analytical value		U *	Acceptable range	Method/Instrument	Traceability
Trglyceride	1.21	mmol/L	0.08	1.13 - 1.29	GPO/PAP	ID-MS
	107.2	mg/dL	7	100.1 - 114		
UIBC	37.6	μmol/L	5.5	32.1 - 43.1	FeroZine®	Primary reference material
	210	μg/dL	31	179 - 241		
Urea	4.26	mmol/L	0.4	3.86 - 4.66	Urease/GLZDH	SRM909b
	11.9	mg/dL	1.1	10.8 - 13.1		
Uric acid	297	μmol/L	19	278 - 316	Uricase/POD	ID-MS
	4.99	mg/dL	0.32	4.67 - 5.31		
Zinc	27.4	μmol/L	2.6	24.8 - 30.0	ICP-MS	SRM 3168a
	179	μg/dL	17	162 - 196		

* (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.