

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 ±3SD range by MEASURE Reagent	JCCRM613 (ERM DA470)
	4.01 g/dL	0.134	3.61 - 4.41		
ALT	42.0 U/L	1.40	37.8 - 46.2	JSCC at 37°C (IFCC w/o PalP) / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
	0.70 µkat/L	0.023	0.63 - 0.77		
ALP IFCC	89.0 U/L	4.5	75.7 - 102	IFCC at 37°C / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d (IFCC)
	1.49 µkat/L	0.074	1.26 - 1.71		
Amylase, total	102 U/L	5.10	86.7 - 117	IFCC at 37°C / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
	1.70 µkat/L	0.085	1.45 - 1.96		
AST	43.0 U/L	1.43	38.7 - 47.3	JSCC at 37°C (IFCC w/o PalP) / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
	0.72 µkat/L	0.024	0.65 - 0.79		
Bilirubin, direct	8.89 µmol/L	0.741	6.67 - 11.1	Enzymatic / Hitachi-7180 ±3SD range by MEASURE Reagent	NIST
	0.52 mg/dL	0.043	0.39 - 0.65		
Bilirubin, total	16.8 µmol/L	0.56	15.1 - 18.4	Enzymatic / Hitachi-7180 ±3SD range by MEASURE Reagent	NIST
	0.98 mg/dL	0.033	0.88 - 1.08		
Cholesterol, total	4.35 mmol/L	0.145	3.92 - 4.79	CHOD-PAP / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM223 (SRM1951a)
	168 mg/dL	5.6	151 - 185		
HDL Cholesterol	1.45 mmol/L	0.097	1.16 - 1.74	Direct enzymatic colorimetry / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM223 (SRM1951a)
	56.1 mg/dL	3.74	44.9 - 67.3		
LDL Cholesterol	2.75 mmol/L	0.137	2.33 - 3.16	Direct enzymatic colorimetry / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM223 (SRM1951a)
	106.0 mg/dL	5.30	90.1 - 122		
CK	93.6 U/L	4.68	79.6 - 108	JSCC at 37°C / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
	1.56 µkat/L	0.078	1.33 - 1.80		
CK-MB	26.9 U/L	3.59	16.1 - 37.7	Immunological UV / Hitachi-7180 ±3SD range by MEASURE Reagent	Internal SOP
	0.45 µkat/L	0.060	0.27 - 0.63		
Creatinine	71.6 µmol/L	3.58	60.9 - 82.3	Enzymatic / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM521 (ID-MS)
	0.81 mg/dL	0.041	0.69 - 0.93		
GGT	38.1 U/L	1.52	33.5 - 42.7	JSCC at 37°C / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
	0.64 µkat/L	0.025	0.56 - 0.71		
Glucose	4.25 mmol/L	0.142	3.82 - 4.67	HK/G6P-DH / Hitachi-7180 HDAOS-POD / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM521 (ID-MS/SRM917)
	76.5 mg/dL	2.55	68.9 - 84.2		
LDH IFCC	145 U/L	4.8	131 - 160	IFCC at 37°C / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
	2.42 µkat/L	0.081	2.18 - 2.66		
Protein, total	63.5 g/L	2.12	57.2 - 69.9	Modified Biuret / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM613 (sm927)
	6.35 g/dL	0.212	5.72 - 6.99		
Trglyceride	0.71 mmol/L	0.024	0.64 - 0.78	GPO/PAP ±3SD range by MEASURE Reagent	JCCRM223 (ID-MS)
	62.1 mg/dL	2.07	55.9 - 68.3		
(TG-T)	1.20 mmol/L	0.040	1.08 - 1.32	GPO/PAP ±3SD range by MEASURE Reagent	JCCRM223 (ID-MS)
	105 mg/dL	3.50	94.5 - 116		
Urea Nitrogen	4.26 mmol/L	0.142	3.84 - 4.69	Urease-UV / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM521 (id-ms/srm912)
	11.9 mg/dL	0.40	10.7 - 13.1		
Uric acid	293 µmol/L	9.8	264 - 323	Uricase-POD / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM521 (ID-MS)
	4.93 mg/dL	0.164	4.44 - 5.42		

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
		

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(Other Method)

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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 phosphomolybdate	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		

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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.