

MEASURE Human Lyo L-1
for MESURE Reagent

Lot. 116ADH

(White Cap)

2°C~8°C EXP. 2026.02.

Manufacture Date : 2023.10.02.

Component	Analytical value		1SD	Acceptable range		Method/Instrument	Traceability
Albumin	41.1	g/L	1.37	37.0	- 45.2	BCG / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM613 (ERM DA470)
	4.11	g/dL	0.137	3.70	- 4.52		
ALT	44.4	U/L	1.48	40.0	- 48.8	JSCC at 37°C (IFCC w/o PaIP) / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
	0.74	µkat/L	0.025	0.67	- 0.82		
ALP	107	U/L	5.3	90.6	- 123	IFCC at 37°C / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d (IFCC)
	1.78	µkat/L	0.089	1.51	- 2.05		
ALP IFCC	95.2	U/L	4.8	80.9	- 109	IFCC at 37°C / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d (IFCC)
	1.59	µkat/L	0.079	1.35	- 1.83		
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	42.0	U/L	1.40	37.8	- 46.2	JSCC at 37°C (IFCC w/o PaIP) / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
	0.70	µkat/L	0.023	0.63	- 0.77		
Bile Acid	18.1	µmol/L	1.81	12.7	- 23.5	Enzymatic (3-α-HDS) / Hitachi-7180 ±3SD range by MEASURE Reagent	Gravimetry
	7.03	mg/L	0.703	4.92	- 9.14		
Bilirubin, direct	9.06	µmol/L	0.755	6.80	- 11.3	Enzymatic / Hitachi-7180 ±3SD range by MEASURE Reagent	NIST
	0.53	mg/dL	0.044	0.40	- 0.66		
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	4.09	mmol/L	0.136	3.68	- 4.50	CHOD-PAP / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM223 (SRM1951a)
	158	mg/dL	5.3	142	- 174		
HDL Cholesterol	1.44	mmol/L	0.096	1.15	- 1.73	Direct enzymatic colorimetry / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM223 (SRM1951a)
	55.6	mg/dL	3.71	44.5	- 66.7		
LDL Cholesterol	2.48	mmol/L	0.124	2.11	- 2.86	Direct enzymatic colorimetry / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM223 (SRM1951a)
	95.9	mg/dL	4.80	81.5	- 110		
CK	97.9	U/L	4.90	83.2	- 113	JSCC at 37°C / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
	1.63	µkat/L	0.082	1.39	- 1.88		
CK-MB	27.3	U/L	3.64	16.4	- 38.2	Immunological UV / Hitachi-7180 ±3SD range by MEASURE Reagent	Internal SOP
	0.46	µkat/L	0.061	0.27	- 0.64		
Creatinine	81.3	µmol/L	4.07	69.1	- 93.5	Enzymatic / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM521 (ID-MS)
	0.92	mg/dL	0.046	0.78	- 1.06		
GGT	37.6	U/L	1.50	33.1	- 42.1	JSCC at 37°C / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
	0.63	µkat/L	0.025	0.55	- 0.70		
Glucose	4.28	mmol/L	0.143	3.85	- 4.71	HDAOS-POD / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM521 (ID-MS/SRM917)
	77.1	mg/dL	2.57	69.4	- 84.8		
LDH	146	U/L	4.9	131	- 160	JSCC at 37°C / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
	2.43	µkat/L	0.081	2.19	- 2.67		
LDH IFCC	150	U/L	5.0	135	- 165	IFCC at 37°C / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
	2.51	µkat/L	0.084	2.25	- 2.76		
Protein, total	64.2	g/L	2.14	57.8	- 70.6	Modified Biuret / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM613 (sm927)
	6.42	g/dL	0.214	5.78	- 7.06		
Trglyceride	0.77	mmol/L	0.026	0.69	- 0.84	GPO/PAP ±3SD range by MEASURE Reagent	JCCRM223 (ID-MS)
	67.2	mg/dL	2.24	60.5	- 73.9		
(TG-T)	1.10	mmol/L	0.037	0.99	- 1.22	GPO/PAP ±3SD range by MEASURE Reagent	JCCRM223 (ID-MS)
	96.9	mg/dL	3.23	87.2	- 107		
Urea Nitrogen	4.76	mmol/L	0.159	4.29	- 5.24	Urease-UV / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM521 (id-ms/srm912)
	13.3	mg/dL	0.44	12.0	- 14.6		
Uric acid	292	µmol/L	9.7	263	- 321	Uricase-POD / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM521 (ID-MS)
	4.91	mg/dL	0.164	4.42	- 5.40		

Acceptable range : ± 3SD

UMA Co.,Ltd.

Tester	Quality Control Manager	Manufacturing Control Manager
		

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Component	Analytical value	U *	Acceptable range	Method/Instrument	Traceability
ALT	45.0 U/L	4	41.0 - 49.0	IFCC 37°C with PalP	IFCC
	0.75 μ kat/L	0.07	0.68 - 0.82		
Albumin	41.4 g/L	3.8	37.6 - 45.2	BCG	CRM470
	4.14 g/dL	0.38	3.76 - 4.52		
ALP	99.0 U/L	10	89.0 - 109	IFCC at 37°C	IFCC
	1.65 μ kat/L	0.17	1.49 - 1.82		
Amylase, total	99.0 U/L	7	92.0 - 106	IFCC at 37°C	IFCC
	1.65 μ kat/L	0.12	1.54 - 1.77		
Amylase, pancreas	49.0 U/L	3	46.0 - 52.0	Enzymatic colorimetry 37°C	
	0.82 μ kat/L	0.05	0.77 - 0.87		
AST	44.0 U/L	4	40.0 - 48.0	IFCC 37°C with PalP	IFCC
	0.73 μ kat/L	0.07	0.67 - 0.80		
Bilirubin, direct	4.70 μ mol/L	0.7	4.00 - 5.40	Diazo	
	0.27 mg/dL	0.04	0.23 - 0.32		
Bilirubin, total	13.7 μ mol/L	2.0	11.7 - 15.7	DPD	Doumas method
	0.80 mg/dL	0.12	0.68 - 0.92		
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	106 mmol/L	5	101 - 111	Indirect ISE	Gravimetry
Cholesterol, total	3.95 mmol/L	0.24	3.71 - 4.19	CHOD/PAP	ID-MS
	153 mg/dL	9	143 - 162		
HDL Cholesterol	1.17 mmol/L	0.22	0.95 - 1.39	Direct enzymatic colorimetry	SRM1951a
	45.2 mg/dL	9	36.7 - 53.8		
LDL Cholesterol	2.30 mmol/L	0.20	2.10 - 2.50	Direct enzymatic colorimetry	SRM1951a
	88.9 mg/dL	8	81.2 - 96.7		
CK	104 U/L	8	96.0 - 112	IFCC at 37°C	IFCC
	1.74 μ kat/L	0.13	1.60 - 1.87		
CK-MB	20.0 U/L	5	15.0 - 25.0	Immunological UV	ERM-AD455/IFCC
	0.33 μ kat/L	0.08	0.25 - 0.42		
Copper	16.1 μ mol/L	1.2	14.9 - 17.3	ICP-MS	SRM 3114
	102 μ g/dL	8	95 - 110		
Creatinine	75.5 μ mol/L	6	69.5 - 81.5	Enzymatic colorimetry	ID-MS
	0.85 mg/dL	0.07	0.79 - 0.92		
Digoxin	0.994 nmol/L			LIA Access	
GGT	36.0 U/L	3	33.0 - 39.0	IFCC at 37°C	IFCC
	0.60 μ kat/L	0.05	0.55 - 0.65		
GLDH	5.20 U/L	0.4	4.80 - 5.60	DGKC 37°C	
	0.09 μ kat/L	0.01	0.08 - 0.09		
Glucose	4.38 mmol/L	0.36	4.02 - 4.74	HK/G6P-DH	ID-MS
	78.9 mg/dL	6	72.4 - 85.4		
Iron	17.9 μ mol/L	1.4	16.5 - 19.3	Ascorbate/FerroZine	SRM937
	99.9 μ g/dL	7.8	92.1 - 108		
Lactate	1.99 mmol/L	0.2	1.79 - 2.19	LOD/POD	Primery reference material
	17.9 mg/dL	1.8	16.1 - 19.7		
LDH	144 U/L	14	130 - 158	IFCC at 37°C	IFCC
	2.40 μ kat/L	0.23	2.17 - 2.64		
Lipase	47.0 U/L	5	42.0 - 52.0	Enzymatic colorimetry 37°C	Roche reagent manual measurement
	0.78 μ kat/L	0.08	0.70 - 0.87		
Lithium	0.795 mmol/L	0.02	0.78 - 0.82	Colorimetry	
	0.55 mg/dL	0.01	0.54 - 0.57		
Magnesium	0.85 mmol/L	0.03	0.82 - 0.88	Xylidyl-blue	Gravimetry
	2.07 mg/dL	0.07	1.99 - 2.14		
Phosphorus	1.01 mmol/L	0.06	0.95 - 1.07	Ammonium phosphomoplybdate	Primary reference material
	3.13 mg/dL	0.19	2.94 - 3.31		
Potassium	3.95 mmol/L	0.15	3.80 - 4.10	Indirect ISE	Gravimetry
Protein total	62.0 g/L	5.1	56.9 - 67.1	Biuret	SRM927c
	6.20 g/dL	0.51	5.69 - 6.71		
Sodium	139 mmol/L	5	134 - 144	Indirect ISE	Gravimetry
Theophylline	71.8 μ mol/L			KIMS	Gravimetry
Total Bile Acid	25.6 μ mol/L	4	21.6 - 29.6	Enzymatic endpoint	
	9.98 mg/L	1.56	8.42 - 11.5		

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Component	Analytical value	U *	Acceptable range	Method/Instrument	Traceability
Trglyceride	1.12 mmol/L	0.08	1.04 - 1.20	GPO/PAP	ID-MS
	99.2 mg/dL	7	92.1 - 106		
UIBC	39.1 μmol/L	5.5	33.6 - 44.6	FeroZine®	Primary reference material
	218 μg/dL	31	188 - 249		
Urea	4.46 mmol/L	0.4	4.06 - 4.86	Urease/GLZDH	SRM909b
	12.5 mg/dL	1.1	11.4 - 13.6		
Uric acid	289 μmol/L	19	270 - 308	Uricase/POD	ID-MS
	4.86 mg/dL	0.32	4.54 - 5.18		
Zinc	27.9 μmol/L	2.6	25.3 - 30.5	ICP-MS	SRM 3168a
	182 μg/dL	17	165 - 199		

* (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.