

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 4.11 g/dL	1.37 0.137	37.0 - 45.2 3.70 - 4.52	BCG / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM613 (ERM DA470)
ALT	44.4 U/L 0.74 μ kat/L	1.48 0.025	40.0 - 48.8 0.67 - 0.82	JSCC at 37°C (IFCC w/o PaIP) / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
ALP	107 U/L 1.78 μ kat/L	5.3 0.089	90.6 - 123 1.51 - 2.05	IFCC at 37°C / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d (IFCC)
ALP IFCC	95.2 U/L 1.59 μ kat/L	4.8 0.079	80.9 - 109 1.35 - 1.83	IFCC at 37°C / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d (IFCC)
Amylase, total	102 U/L 1.70 μ kat/L	5.10 0.085	86.7 - 117 1.45 - 1.96	IFCC at 37°C / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
AST	42.0 U/L 0.70 μ kat/L	1.40 0.023	37.8 - 46.2 0.63 - 0.77	JSCC at 37°C (IFCC w/o PaIP) / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
Bile Acid	18.1 μ mol/L 7.03 mg/L	1.81 0.703	12.7 - 23.5 4.92 - 9.14	Enzymatic (3- α -HDS) / Hitachi-7180 ±3SD range by MEASURE Reagent	Gravimetry
Bilirubin, direct	9.06 μ mol/L 0.53 mg/dL	0.755 0.044	6.80 - 11.3 0.40 - 0.66	Enzymatic / Hitachi-7180 ±3SD range by MEASURE Reagent	NIST
Bilirubin, total	16.8 μ mol/L 0.98 mg/dL	0.56 0.033	15.1 - 18.4 0.88 - 1.08	Enzymatic / Hitachi-7180 ±3SD range by MEASURE Reagent	NIST
Cholesterol, total	4.09 mmol/L 158 mg/dL	0.136 5.3	3.68 - 4.50 142 - 174	CHOD-PAP / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM223 (SRM1951a)
HDL Cholesterol	1.44 mmol/L 55.6 mg/dL	0.096 3.71	1.15 - 1.73 44.5 - 66.7	Direct enzymatic colorimetry / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM223 (SRM1951a)
LDL Cholesterol	2.48 mmol/L 95.9 mg/dL	0.124 4.80	2.11 - 2.86 81.5 - 110	Direct enzymatic colorimetry / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM223 (SRM1951a)
CK	97.9 U/L 1.63 μ kat/L	4.90 0.082	83.2 - 113 1.39 - 1.88	JSCC at 37°C / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
CK-MB	27.3 U/L 0.46 μ kat/L	3.64 0.061	16.4 - 38.2 0.27 - 0.64	Immunological UV / Hitachi-7180 ±3SD range by MEASURE Reagent	Internal SOP
Creatinine	81.3 μ mol/L 0.92 mg/dL	4.07 0.046	69.1 - 93.5 0.78 - 1.06	Enzymatic / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM521 (ID-MS)
GGT	37.6 U/L 0.63 μ kat/L	1.50 0.025	33.1 - 42.1 0.55 - 0.70	JSCC at 37°C / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
Glucose	4.28 mmol/L 77.1 mg/dL	0.143 2.57	3.85 - 4.71 69.4 - 84.8	HDAOS-POD / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM521 (ID-MS/SRM917)
LDH	146 U/L 2.43 μ kat/L	4.9 0.081	131 - 160 2.19 - 2.67	JSCC at 37°C / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
LDH IFCC	150 U/L 2.51 μ kat/L	5.0 0.084	135 - 165 2.25 - 2.76	IFCC at 37°C / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
Protein, total	64.2 g/L 6.42 g/dL	2.14 0.214	57.8 - 70.6 5.78 - 7.06	Modified Biuret / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM613 (sm927)
Trglyceride	0.77 mmol/L 67.2 mg/dL	0.026 2.24	0.69 - 0.84 60.5 - 73.9	GPO/PAP ±3SD range by MEASURE Reagent	JCCRM223 (ID-MS)
(TG-T)	1.10 mmol/L 96.9 mg/dL	0.037 3.23	0.99 - 1.22 87.2 - 107	GPO/PAP ±3SD range by MEASURE Reagent	JCCRM223 (ID-MS)
Urea Nitrogen	4.76 mmol/L 13.3 mg/dL	0.159 0.44	4.29 - 5.24 12.0 - 14.6	Urease-UV / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM521 (id-ms/srm912)
Uric acid	292 μ mol/L 4.91 mg/dL	9.7 0.164	263 - 321 4.42 - 5.40	Uricase-POD / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM521 (ID-MS)

Acceptable range : $\pm 3SD$

UMA Co.,Ltd.

Tester	Quality Control Manager	Manufacturing Control Manager
		

MEASURE Human Lyo L-1**(Other Method)****Lot. 116ADH****(White Cap)****2°C ~ 8°C****EXP. 2026.02.****Manufacture Date : 2023.10.02.**

Component	Analytical value		U *	Acceptable range	Method/Instrument	Traceability
ALT	45.0 0.75	U/L μkat/L	4 0.07	41.0 - 49.0 0.68 - 0.82	IFCC 37°C with PalP	IFCC
Albumin	41.4 4.14	g/L g/dL	3.8 0.38	37.6 - 45.2 3.76 - 4.52	BCG	CRM470
ALP	99.0 1.65	U/L μkat/L	10 0.17	89.0 - 109 1.49 - 1.82	IFCC at 37°C	IFCC
Amylase, total	99.0 1.65	U/L μkat/L	7 0.12	92.0 - 106 1.54 - 1.77	IFCC at 37°C	IFCC
Amylase, pancreas	49.0 0.82	U/L μkat/L	3 0.05	46.0 - 52.0 0.77 - 0.87	Enzymatic colorimetry 37°C	
AST	44.0 0.73	U/L μkat/L	4 0.07	40.0 - 48.0 0.67 - 0.80	IFCC 37°C with PalP	IFCC
Bilirubin, direct	4.70 0.27	μmol/L mg/dL	0.7 0.04	4.00 - 5.40 0.23 - 0.32	Diazo	
Bilirubin, total	13.7 0.80	μmol/L mg/dL	2.0 0.12	11.7 - 15.7 0.68 - 0.92	DPD	Doumas method
Calucium	2.17 8.70	mmol/L mg/dL	0.15 0.60	2.02 - 2.32 8.10 - 9.30	NM-BAPTA	SRM909b
Chloride	106	mmol/L	5	101 - 111	Indirect ISE	Gravimetry
Cholesterol, total	3.95 153	mmol/L mg/dL	0.24 9	3.71 - 4.19 143 - 162	CHOD/PAP	ID-MS
HDL Cholesterol	1.17 45.2	mmol/L mg/dL	0.22 9	0.95 - 1.39 36.7 - 53.8	Direct enzymatic colorimetry	SRM1951a
LDL Cholesterol	2.30 88.9	mmol/L mg/dL	0.20 8	2.10 - 2.50 81.2 - 96.7	Direct enzymatic colorimetry	SRM1951a
CK	104 1.74	U/L μkat/L	8 0.13	96.0 - 112 1.60 - 1.87	IFCC at 37°C	IFCC
CK-MB	20.0 0.33	U/L μkat/L	5 0.08	15.0 - 25.0 0.25 - 0.42	Immunological UV	ERM-AD455/IFCC
Copper	16.1 102	μmol/L μg/dL	1.2 8	14.9 - 17.3 95 - 110	ICP-MS	SRM 3114
Creatinine	75.5 0.85	μmol/L mg/dL	6 0.07	69.5 - 81.5 0.79 - 0.92	Enzymatic colorimetry	ID-MS
Digoxin	0.994	nmol/L			LIA Access	
GGT	36.0 0.60	U/L μkat/L	3 0.05	33.0 - 39.0 0.55 - 0.65	IFCC at 37°C	IFCC
GLDH	5.20 0.09	U/L μkat/L	0.4 0.01	4.80 - 5.60 0.08 - 0.09	DGKC 37°C	
Glucose	4.38 78.9	mmol/L mg/dL	0.36 6	4.02 - 4.74 72.4 - 85.4	HK/G6P-DH	ID-MS
Iron	17.9 99.9	μmol/L μg/dL	1.4 7.8	16.5 - 19.3 92.1 - 108	Ascorbate/FerroZine	SRM937
Lactate	1.99 17.9	mmol/L mg/dL	0.2 1.8	1.79 - 2.19 16.1 - 19.7	LOD/POD	Primery reference material
LDH	144 2.40	U/L μkat/L	14 0.23	130 - 158 2.17 - 2.64	IFCC at 37°C	IFCC
Lipase	47.0 0.78	U/L μkat/L	5 0.08	42.0 - 52.0 0.70 - 0.87	Enzymatic colorimetry 37°C	Roche reagent manual measurement
Lithium	0.795 0.55	mmol/L mg/dL	0.02 0.01	0.78 - 0.82 0.54 - 0.57	Colorimetry	
Magnesium	0.85 2.07	mmol/L mg/dL	0.03 0.07	0.82 - 0.88 1.99 - 2.14	Xylidyl-blue	Gravimetry
Phosphorus	1.01 3.13	mmol/L mg/dL	0.06 0.19	0.95 - 1.07 2.94 - 3.31	Ammonium phosphomoplybdate	Primary reference material
Potassium	3.95	mmol/L	0.15	3.80 - 4.10	Indirect ISE	Gravimetry
Protein total	62.0 6.20	g/L g/dL	5.1 0.51	56.9 - 67.1 5.69 - 6.71	Biuret	SRM927c
Sodium	139	mmol/L	5	134 - 144	Indirect ISE	Gravimetry
Theophylline	71.8	μmol/L			KIMS	Gravimetry
Total Bite Acid	25.6 9.98	μmol/L mg/L	4 1.56	21.6 - 29.6 8.42 - 11.5	Enzymatic endpoint	

MEASURE Human Lyo L-1

(Other Method)

Lot. 116ADH

(White Cap)

2°C~ 8°C

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Manufacture Date : 2023.10.02.

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.