

MEASURE Human Lyo L-1**for MESURE Reagent****Lot. 114ACE****(White Cap)****2°C~8°C****EXP. 2024.11.****Manufacture Date : 2023.05.01.**

Component	Analytical value	1SD	Acceptable range	Method/Instrument	Traceability
Albumin	40.9 g/L	1.36	36.8 - 45.0	BCG / Hitachi-7180	JCCRM613
	4.09 g/dL	0.136	3.68 - 4.50	±3SD range by MEASURE Reagent	(ERM DA470)
ALT	44.2 U/L	1.47	39.8 - 48.6	JSCC at 37°C (IFCC w/o PaIP) / Hitachi-7180	JCCRM001d
	0.74 μ kat/L	0.025	0.66 - 0.81	±3SD range by MEASURE Reagent	
ALP	109 U/L	5.4	92.3 - 125	IFCC at 37°C / Hitachi-7180	JCCRM001d (IFCC)
	1.81 μ kat/L	0.091	1.54 - 2.09	±3SD range by MEASURE Reagent	
ALP IFCC	97.0 U/L	4.9	82.5 - 112	IFCC at 37°C / Hitachi-7180	JCCRM001d (IFCC)
	1.62 μ kat/L	0.081	1.38 - 1.86	±3SD range by MEASURE Reagent	
Amylase, total	102 U/L	5.10	86.7 - 117	IFCC at 37°C / Hitachi-7180	JCCRM001d
	1.70 μ kat/L	0.085	1.45 - 1.96	±3SD range by MEASURE Reagent	
AST	40.8 U/L	1.36	36.7 - 44.9	JSCC at 37°C (IFCC w/o PaIP) / Hitachi-7180	JCCRM001d
	0.68 μ kat/L	0.023	0.61 - 0.75	±3SD range by MEASURE Reagent	
Bile Acid	19.7 μ mol/L	1.97	13.8 - 25.6	Enzymatic (3- α -HDS) / Hitachi-7180	Gravimetry
	7.65 mg/L	0.765	5.36 - 9.95	±3SD range by MEASURE Reagent	
Bilirubin, direct	9.06 μ mol/L	0.755	6.80 - 11.3	Enzymatic / Hitachi-7180	NIST
	0.53 mg/dL	0.044	0.40 - 0.66	±3SD range by MEASURE Reagent	
Bilirubin, total	15.9 μ mol/L	0.53	14.3 - 17.5	Enzymatic / Hitachi-7180	NIST
	0.93 mg/dL	0.031	0.84 - 1.02	±3SD range by MEASURE Reagent	
Cholesterol, total	4.12 mmol/L	0.137	3.71 - 4.53	CHOD-PAP / Hitachi-7180	JCCRM223
	159 mg/dL	5.3	143 - 175	±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	2.41 mmol/L	0.121	2.05 - 2.77	Direct enzymatic colorimetry / Hitachi-7180	JCCRM223
	93.1 mg/dL	4.66	79.1 - 107	±3SD range by MEASURE Reagent	(SRM1951a)
CK	96.0 U/L	4.80	81.6 - 110	JSCC at 37°C / Hitachi-7180	JCCRM001d
	1.60 μ kat/L	0.080	1.36 - 1.84	±3SD range by MEASURE Reagent	
CK-MB	26.6 U/L	3.55	16.0 - 37.2	Immunological UV / Hitachi-7180	Internal SOP
	0.44 μ kat/L	0.059	0.27 - 0.62	±3SD range by MEASURE Reagent	
Creatinine	77.8 μ mol/L	3.89	66.1 - 89.5	Enzymatic / Hitachi-7180	JCCRM521
	0.88 mg/dL	0.044	0.75 - 1.01	±3SD range by MEASURE Reagent	(ID-MS)
GGT	37.0 U/L	1.48	32.6 - 41.4	JSCC at 37°C / Hitachi-7180	JCCRM001d
	0.62 μ kat/L	0.025	0.54 - 0.69	±3SD range by MEASURE Reagent	
Glucose	4.27 mmol/L	0.142	3.85 - 4.70	HDAOS-POD / Hitachi-7180	JCCRM521
	77.0 mg/dL	2.57	69.3 - 84.7	±3SD range by MEASURE Reagent	(ID-MS/SRM917)
LDH	144 U/L	4.8	129 - 158	JSCC at 37°C / Hitachi-7180	JCCRM001d
	2.40 μ kat/L	0.080	2.16 - 2.64	±3SD range by MEASURE Reagent	
LDH IFCC	148 U/L	4.9	133 - 163	IFCC at 37°C / Hitachi-7180	JCCRM001d
	2.47 μ kat/L	0.082	2.22 - 2.72	±3SD range by MEASURE Reagent	
Protein, total	63.1 g/L	2.10	56.8 - 69.4	Modified Biuret / Hitachi-7180	JCCRM613
	6.31 g/dL	0.210	5.68 - 6.94	±3SD range by MEASURE Reagent	(srm927)
Trglyceride	0.72 mmol/L	0.024	0.65 - 0.79	GPO/PAP	JCCRM223
	62.9 mg/dL	2.10	56.6 - 69.2	±3SD range by MEASURE Reagent	(ID-MS)
(TG-T)	1.08 mmol/L	0.036	0.97 - 1.19	GPO/PAP	JCCRM223
	95.0 mg/dL	3.17	85.5 - 105	±3SD range by MEASURE Reagent	(ID-MS)
Urea Nitrogen	4.83 mmol/L	0.161	4.35 - 5.32	Urease-UV / Hitachi-7180	JCCRM521
	13.5 mg/dL	0.45	12.2 - 14.9	±3SD range by MEASURE Reagent	(id-ms/srm912)
Uric acid	298 μ mol/L	9.9	268 - 327	Uricase-POD / Hitachi-7180	JCCRM521
	5.00 mg/dL	0.167	4.50 - 5.50	±3SD range by MEASURE Reagent	(ID-MS)

Acceptable range : $\pm 3SD$

MEASURE Human Lyo L-1**(Other Method)**

VH

Lot. 114ACE**(White Cap)****2°C ~ 8°C****EXP. 2024.11.****Manufacture Date : 2023.05.01.**

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 PaIP	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 PaIP	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	Primary 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 phosphomolybdate	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 Bile 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)

VH

Lot. 114ACE

(White Cap)

2°C~ 8°C

EXP. 2024.11.

Manufacture Date : 2023.05.01.

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,