

MEASURE Human Lyo L-1**for MESURE Reagent****Lot. 116AEL****(White Cap)****2°C~8°C****EXP. 2027.06.**

Component	Analytical value		1SD	Acceptable range		Method/Instrument	Traceability
Albumin	41.1	g/L	1.37	37.0	~ 45.2	BCG / Hitachi-7180	JCCRM613
	4.11	g/dL	0.137	3.70	~ 4.52	±3SD range by MEASURE Reagent	(ERM DA470)
ALT	44.4	U/L	1.48	40.0	~ 48.8	JSCC at 37°C (IFCC w/o PalP) / Hitachi-7180	JCCRM001d
	0.74	μkat/L	0.025	0.67	~ 0.82	±3SD range by MEASURE Reagent	
ALP IFCC	95.2	U/L	4.8	80.9	~ 109	IFCC at 37°C / Hitachi-7180	JCCRM001d (IFCC)
	1.59	μkat/L	0.079	1.35	~ 1.83	±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	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	
Bile Acid	18.1	μmol/L	1.81	12.7	~ 23.5	Enzymatic (3-α-HDS) / Hitachi-7180	Gravimetry
	7.03	mg/L	0.703	4.92	~ 9.14	±3SD range by MEASURE Reagent	
Bilirubin, direct	9.06	μmol/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	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	4.09	mmol/L	0.136	3.68	~ 4.50	CHOD-PAP / Hitachi-7180	JCCRM223
	158	mg/dL	5.3	142	~ 174	±3SD range by MEASURE Reagent	(SRM1951a)
HDL Cholesterol	1.44	mmol/L	0.096	1.15	~ 1.73	Direct enzymatic colorimetry / Hitachi-7180	JCCRM223
	55.6	mg/dL	3.71	44.5	~ 66.7	±3SD range by MEASURE Reagent	(SRM1951a)
LDL Cholesterol	2.48	mmol/L	0.124	2.11	~ 2.86	Direct enzymatic colorimetry / Hitachi-7180	JCCRM223
	95.9	mg/dL	4.80	81.5	~ 110	±3SD range by MEASURE Reagent	(SRM1951a)
CK	97.9	U/L	4.90	83.2	~ 113	JSCC at 37°C / Hitachi-7180	JCCRM001d
	1.63	μkat/L	0.082	1.39	~ 1.88	±3SD range by MEASURE Reagent	
CK-MB	27.3	U/L	3.64	16.4	~ 38.2	Immunological UV / Hitachi-7180	Internal SOP
	0.46	μkat/L	0.061	0.27	~ 0.64	±3SD range by MEASURE Reagent	
Creatinine	81.3	μmol/L	4.07	69.1	~ 93.5	Enzymatic / Hitachi-7180	JCCRM521
	0.92	mg/dL	0.046	0.78	~ 1.06	±3SD range by MEASURE Reagent	(ID-MS)
GGT	37.6	U/L	1.50	33.1	~ 42.1	JSCC at 37°C / Hitachi-7180	JCCRM001d
	0.63	μkat/L	0.025	0.55	~ 0.70	±3SD range by MEASURE Reagent	
Glucose	4.28	mmol/L	0.143	3.85	~ 4.71	HK/G6P-DH / Hitachi-7180	JCCRM521
	77.1	mg/dL	2.57	69.4	~ 84.8	HDAOS-POD / Hitachi-7180	(ID-MS/SRM917)
LDH IFCC	150	U/L	5.0	135	~ 165	IFCC at 37°C / Hitachi-7180	JCCRM001d
	2.51	μkat/L	0.084	2.25	~ 2.76	±3SD range by MEASURE Reagent	
Protein, total	64.2	g/L	2.14	57.8	~ 70.6	Modified Biuret / Hitachi-7180	JCCRM613
	6.42	g/dL	0.214	5.78	~ 7.06	±3SD range by MEASURE Reagent	(sm927)
Trglyceride	0.77	mmol/L	0.026	0.69	~ 0.84	GPO/PAP	JCCRM223
	67.2	mg/dL	2.24	60.5	~ 73.9	±3SD range by MEASURE Reagent	(ID-MS)
(TG-T)	1.10	mmol/L	0.037	0.99	~ 1.22	GPO/PAP	JCCRM223
	96.9	mg/dL	3.23	87.2	~ 107	±3SD range by MEASURE Reagent	(ID-MS)
Urea Nitrogen	4.76	mmol/L	0.159	4.29	~ 5.24	Urease-UV / Hitachi-7180	JCCRM521
	13.3	mg/dL	0.44	12.0	~ 14.6	±3SD range by MEASURE Reagent	(id-ms/srm912)
Uric acid	292	μmol/L	9.7	263	~ 321	Uricase-POD / Hitachi-7180	JCCRM521
	4.91	mg/dL	0.164	4.42	~ 5.40	±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. 116AEL****(White Cap)****2°C ~ 8°C****EXP. 2027.06.**

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	μkat/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	μkat/L	0.17	1.49	- 1.82		
Amylase, total	99.0	U/L	7	92.0	- 106	IFCC at 37°C	IFCC
	1.65	μkat/L	0.12	1.54	- 1.77		
Amylase, pancreas	49.0	U/L	3	46.0	- 52.0	Enzymatic colorimetry 37°C	
	0.82	μkat/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	μkat/L	0.07	0.67	- 0.80		
Bilirubin, direct	4.70	μmol/L	0.7	4.00	- 5.40	Diazo	
	0.27	mg/dL	0.04	0.23	- 0.32		
Bilirubin, total	13.7	μmol/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	μkat/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	μkat/L	0.08	0.25	- 0.42		
Copper	16.1	μmol/L	1.2	14.9	- 17.3	ICP-MS	SRM 3114
	102	μg/dL	8	95	- 110		
Creatinine	75.5	μmol/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	μkat/L	0.05	0.55	- 0.65		
GLDH	5.20	U/L	0.4	4.80	- 5.60	DGKC 37°C	
	0.09	μkat/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	μmol/L	1.4	16.5	- 19.3	Ascorbate/FerroZine	SRM937
	99.9	μg/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	μkat/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	μkat/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	μmol/L				KIMS	Gravimetry
Total Bile Acid	25.6	μmol/L	4	21.6	- 29.6	Enzymatic endpoint	
	9.98	mg/L	1.56	8.42	- 11.5		

MEASURE Human Lyo L-1**(Other Method)****Lot. 116AEL****(White Cap)****2°C~ 8°C****EXP. 2027.06.**

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, Estradiol, Ferritin, Folate, HBDH, β-HCG, Homocysteine, IgA, IgG, IgM, NEFA, Osmolality, Phospholipids, Progesterone, f-T3,T3,f-T4,T4,Testosteron, Transferrin, TSH,