

MEASURE Human Lyo L-2 for MEASURE Reagent

Lot. 215ACJ

(Blue Cap)

2°C~8°C

EXP. 2025.04.

Manufacture Date : 2023.10.02.

Component	Analytical value	1SD	Acceptable range	Method/Instrument	Traceability
Albumin	63.1 g/L 6.31 g/dL	2.10 0.210	56.8 - 69.4 5.68 - 6.94	BCG / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM613 (ERM DA470)
ALT	150 U/L 2.51 μkat/L	5.00 0.084	135 - 165 2.25 - 2.76	JSCC at 37°C (IFCC w/o PaIP) / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
ALP	358 U/L 5.99 μkat/L	17.9 0.299	305 - 412 5.09 - 6.88	IFCC at 37°C / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d (IFCC)
ALP IFCC	320 U/L 5.34 μkat/L	16.0 0.267	272 - 368 4.54 - 6.15	IFCC at 37°C / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d (IFCC)
Amylase, total	399 U/L 6.66 μkat/L	19.95 0.333	339 - 459 5.66 - 7.66	IFCC at 37°C / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
AST	229 U/L 3.82 μkat/L	7.63 0.127	206 - 252 3.44 - 4.21	JSCC at 37°C (IFCC w/o PaIP) / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
Bile Acid	110 μmol/L 42.7 mg/L	11.00 4.274	77.0 - 143 29.9 - 55.6	Enzymatic (3-α-HDS) / Hitachi-7180 ±3SD range by MEASURE Reagent	Gravimetry
Bilirubin, direct	39.5 μmol/L 2.31 mg/dL	2.633 0.132	31.6 - 47.4 1.85 - 2.77	Enzymatic / Hitachi-7180 ±3SD range by MEASURE Reagent	NIST
Bilirubin, total	72.0 μmol/L 4.21 mg/dL	2.40 0.140	64.8 - 79.2 3.79 - 4.63	Enzymatic / Hitachi-7180 ±3SD range by MEASURE Reagent	NIST
Cholesterol, total	6.22 mmol/L 240 mg/dL	0.207 8.0	5.59 - 6.84 216 - 264	CHOD-PAP / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM223 (SRM1951a)
HDL Cholesterol ^(*)	1.12 mmol/L 43.3 mg/dL	0.075 2.89	0.90 - 1.35 34.6 - 52.0	Direct enzymatic colorimetry / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM223 (SRM1951a)
LDL Cholesterol	3.68 mmol/L 142 mg/dL	0.184 7.10	3.13 - 4.23 121 - 163	Direct enzymatic colorimetry / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM223 (SRM1951a)
CK	307 U/L 5.13 μkat/L	15.35 0.256	261 - 353 4.36 - 5.90	JSCC at 37°C / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
CK-MB	68.1 U/L 1.14 μkat/L	9.08 0.152	40.9 - 95.3 0.68 - 1.59	Immunological UV / Hitachi-7180 ±3SD range by MEASURE Reagent	Internal SOP
Creatinine	276 μmol/L 3.12 mg/dL	11.03 0.125	243 - 309 2.75 - 3.49	Enzymatic / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM521 (ID-MS)
GGT	150 U/L 2.51 μkat/L	6.00 0.301	132 - 168 2.20 - 2.81	JSCC at 37°C / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
Glucose	10.8 mmol/L 194 mg/dL	0.359 6.47	9.69 - 11.8 175 - 213	HDAOS-POD / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM521 (ID-MS/SRM917)
LDH	332 U/L 5.54 μkat/L	11.1 0.185	299 - 365 4.99 - 6.09	JSCC at 37°C / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
LDH IFCC	342 U/L 5.71 μkat/L	11.4 0.190	308 - 376 5.14 - 6.28	IFCC at 37°C / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
Protein, total	101 g/L 10.1 g/dL	3.37 0.337	90.9 - 111 9.09 - 11.1	Modified Biuret / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM613 (sm927)
Trglyceride	1.01 mmol/L 88.4 mg/dL	0.034 2.95	0.91 - 1.11 79.6 - 97	GPO/PAP ±3SD range by MEASURE Reagent	JCCRM223 (ID-MS)
(TG-T)	5.02 mmol/L 440 mg/dL	0.167 14.67	4.51 - 5.52 396 - 484	GPO/PAP ±3SD range by MEASURE Reagent	JCCRM223 (ID-MS)
Urea Nitrogen	13.2 mmol/L 36.9 mg/dL	0.440 1.23	11.9 - 14.5 33.2 - 40.6	Urease-UV / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM521 (id-ms/srm912)
Uric acid	702 μmol/L 11.8 mg/dL	23.4 0.393	632 - 772 10.6 - 13.0	Uricase-POD / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM521 (ID-MS)

Acceptable range : ± 3SD

HDL Cholesyerol value is Provisional value

MEASURE Human Lyo L-2**(Other Method)****Lot. 215ACJ****(Blue Cap)****2°C ~ 8°C****EXP. 2025.04.****Manufacture Date : 2023.10.02.**

Component	Analytical value		U	Acceptable range		Method/Instrument	Traceability
ALT	156	U/L	17	139	- 173	IFCC 37°C with PalP	IFCC
	2.61	μkat/L	0.28	2.32	- 2.89		
Albumin	59.4	g/L	4.8	54.6	- 64.2	BCG	CRM470
	5.94	g/dL	0.38	5.56	- 6.32		
ALP	296	U/L	27	269	- 323	IFCC at 37°C	IFCC
	4.94	μkat/L	0.45	4.49	- 5.39		
Amylase, total	382	U/L	25	357	- 407	IFCC at 37°C	IFCC
	6.38	μkat/L	0.42	5.96	- 6.80		
Amylase, pancreas	192	U/L	15	177	- 207	Enzymatic colorimetry 37°C	
	3.21	μkat/L	0.25	2.96	- 3.46		
AST	240	U/L	20	220	- 260	IFCC 37°C with PalP	IFCC
	4.01	μkat/L	0.33	3.67	- 4.34		
Bilirubin, direct	16.8	μmol/L	1.6	15.2	- 18.4	Diazo	
	0.98	mg/dL	0.09	0.89	- 1.08		
Bilirubin, total	73.5	μmol/L	8.1	65.4	- 81.6	DPD	Doumas method
	4.30	mg/dL	0.47	3.82	- 4.77		
Calucium	3.19	mmol/L	0.15	3.04	- 3.34	NM-BAPTA	SRM909b
	12.79	mg/dL	0.60	12.18	- 13.39		
Chloride	130	mmol/L	6	124	- 136	Indirect ISE	Gravimetry
Cholesterol, total	5.77	mmol/L	0.47	5.30	- 6.24	CHOD/PAP	ID-MS
	223	mg/dL	18	205	- 241		
HDL Cholesterol	1.73	mmol/L	0.22	1.51	- 1.95	Direct enzymatic colorimetry	SRM1951a
	66.9	mg/dL	9	58.4	- 75.4		
LDL Cholesterol	3.63	mmol/L	0.34	3.29	- 3.97	Direct enzymatic colorimetry	SRM1951a
	140	mg/dL	13	127	- 154		
CK	335	U/L	44	291	- 379	IFCC at 37°C	IFCC
	5.59	μkat/L	0.73	4.86	- 6.33		
CK-MB	54.0	U/L	13	41.0	- 67.0	Immunological UV	ERM-AD455/IFCC
	0.90	μkat/L	0.22	0.68	- 1.12		
Copper	34.4	μmol/L	3	31.4	- 37.4	ICP-MS	SRM 3114
Creatinine	266	μmol/L	20	246	- 286	Enzymatic colorimetry	ID-MS
	3.01	mg/dL	0.23	2.78	- 3.24		
Digoxin	2.34	nmol/L				LIA Access	
GGT	147	U/L	10	137	- 157	IFCC at 37°C	IFCC
	2.45	μkat/L	0.17	2.29	- 2.62		
GLDH	9.05	U/L	1.0	8.05	- 10.1	DGKC 37°C	
	0.15	μkat/L	0.02	0.13	- 0.17		
Glucose	10.7	mmol/L	0.9	9.80	- 11.6	HK/G6P-DH	ID-MS
	193	mg/dL	16	177	- 209		
Iron	34.3	μmol/L	2.7	31.6	- 37.0	Ascorbate/FerroZine	SRM937
	192	μg/dL	15.1	176	- 207		
Lactate	5.89	mmol/L	0.4	5.49	- 6.29	LOD/POD	Primery reference material
	53.1	mg/dL	3.6	49.5	- 56.7		
LDH	335	U/L	40	295	- 375	IFCC at 37°C	IFCC
	5.59	μkat/L	0.67	4.93	- 6.26		
Lipase	106	U/L	11	95.0	- 117	Enzymatic colorimetry 37°C	Roche reagent manual measurement
	1.77	μkat/L	0.18	1.59	- 1.95		
Lithium	1.98	mmol/L	0.05	1.93	- 2.03	Colorimetry	
	1.37	mg/dL	0.03	1.34	- 1.41		
Magnesium	1.46	mmol/L	0.11	1.35	- 1.57	Xylidyl-blue	Gravimetry
	3.55	mg/dL	0.27	3.28	- 3.82		
Phosphorus	2.96	mmol/L	0.17	2.79	- 3.13	Ammonium phosphomolybdate	Primary reference material
	9.17	mg/dL	0.53	8.64	- 9.69		
Potassium	6.00	mmol/L	0.34	5.66	- 6.34	Indirect ISE	Gravimetry
Protein total	97.4	g/L	8	89.4	- 105	Biuret	SRM927c
	9.74	g/dL	0.8	8.94	- 10.54		
Sodium	156	mmol/L	6	150	- 162	Indirect ISE	Gravimetry
Theophylline	132	μmol/L				KIMS	Gravimetry
Total Bile Acid	123	μmol/L	21	102	- 144	Enzymatic endpoint	
	48.0	mg/L	8.19	39.8	- 56.2		
Trglyceride	4.76	mmol/L	0.4	4.36	- 5.16	GPO/PAP	ID-MS

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Component	Analytical value		U	Acceptable range		Method/Instrument	Traceability
	422	mg/dL	35	386	- 457		
UIBC	56.1	μmol/L	5.8	50.3	- 61.9	FeroZine®	Primary reference material
	313	μg/dL	32	281	- 346		
Urea	12.6	mmol/L	1.2	11.4	- 13.8	Urease/GLZDH	SRM909b
	35.3	mg/dL	3.4	31.9	- 38.7		
Uric acid	675	μmol/L	62	613	- 737	Uricase/POD	ID-MS
	11.3	mg/dL	1.04	10.3	- 12.4		
Zinc	38.6	μmol/L	2.1	36.5	- 40.7	ICP-MS	SRM 3168a
	252	μg/dL	14	239	- 266		

*(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.