MEASURE Human Lyo L-1
for MESURE Reagent

Lot. 115ACJ (White Cap)

2℃～8℃ EXP. 2025.04. Manufacture Date : 2023.10.02.

Component	Analytical value		1SD	Acceptable range	Method/Instrument	Traceability
Albumin	**40.8**	**g/L**	**1.36**	**36.7 - 44.9**	**BCG / Hitachi-7180**	JCCRM613
	4.08	g/dL	0.136	3.67 - 4.49	±3SD range by MEASURE Reagent	(ERM DA470)
ALT	**44.5**	**U/L**	**1.48**	**40.1 - 49.0**	**JSCC at 37℃ (IFCC w/o PalP) / Hitachi-7180**	JCCRM001d
	0.74	µkat/L	0.025	0.67 - 0.82	±3SD range by MEASURE Reagent	
ALP	**108**	**U/L**	**5.4**	**91.4 - 124**	**IFCC at 37℃ / Hitachi-7180**	JCCRM001d (IFCC)
	1.80	µkat/L	0.090	1.53 - 2.06	±3SD range by MEASURE Reagent	
ALP IFCC	**96.0**	**U/L**	**4.8**	**81.6 - 110**	**IFCC at 37℃ / Hitachi-7180**	JCCRM001d (IFCC)
	1.60	µkat/L	0.080	1.36 - 1.84	±3SD range by MEASURE Reagent	
Amylase, total	**103**	**U/L**	**5.15**	**87.6 - 118**	**IFCC at 37℃ / Hitachi-7180**	JCCRM001d
	1.72	µkat/L	0.086	1.46 - 1.98	±3SD range by MEASURE Reagent	
AST	**40.9**	**U/L**	**1.36**	**36.8 - 45.0**	**JSCC at 37℃ (IFCC w/o PalP) / Hitachi-7180**	JCCRM001d
	0.68	µkat/L	0.023	0.61 - 0.75	±3SD range by MEASURE Reagent	
Bile Acid	**19.3**	**µmol/L**	**1.93**	**13.5 - 25.1**	**Enzymatic (3-α-HDS) / Hitachi-7180**	Gravimetry
	7.50	mg/L	0.750	5.25 - 9.75	±3SD range by MEASURE Reagent	
Bilirubin, direct	**8.55**	**µmol/L**	**0.713**	**6.41 - 10.7**	**Enzymatic / Hitachi-7180**	NIST
	0.50	mg/dL	0.042	0.38 - 0.63	±3SD range by MEASURE Reagent	
Bilirubin, total	**16.1**	**µmol/L**	**0.54**	**14.5 - 17.7**	**Enzymatic / Hitachi-7180**	NIST
	0.94	mg/dL	0.031	0.85 - 1.03	±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	**1.37**	**mmol/L**	**0.092**	**1.10 - 1.65**	**Direct enzymatic colorimetry / Hitachi-7180**	JCCRM223
	53.0	mg/dL	3.53	42.4 - 63.6	±3SD range by MEASURE Reagent	(SRM1951a)
LDL Cholesterol	**2.50**	**mmol/L**	**0.125**	**2.12 - 2.87**	**Direct enzymatic colorimetry / Hitachi7180**	JCCRM223
	96.5	mg/dL	4.83	82.0 - 111	±3SD range by MEASURE Reagent	(SRM1951a)
CK	**90.9**	**U/L**	**4.55**	**77.3 - 105**	**JSCC at 37℃ / Hitachi-7180**	JCCRM001d
	1.52	µkat/L	0.076	1.29 - 1.75	±3SD range by MEASURE Reagent	
CK-MB	**26.2**	**U/L**	**3.49**	**15.7 - 36.7**	**Immunological UV / Hitachi-7180**	Internal SOP
	0.44	µkat/L	0.058	0.26 - 0.61	±3SD range by MEASURE Reagent	
Creatinine	**78.7**	**µmol/L**	**3.93**	**66.9 - 90.5**	**Enzymatic / Hitachi-7180**	JCCRM521
	0.89	mg/dL	0.045	0.76 - 1.02	±3SD range by MEASURE Reagent	(ID-MS)
GGT	**37.0**	**U/L**	**1.48**	**32.6 - 41.4**	**JSCC at 37℃ / Hitachi-7180**	JCCRM001d
	0.62	µkat/L	0.025	0.54 - 0.69	±3SD range by MEASURE Reagent	
Glucose	**4.41**	**mmol/L**	**0.147**	**3.97 - 4.85**	**HDAOS-POD / Hitachi-7180**	JCCRM521
	79.5	mg/dL	2.65	71.6 - 87.5	±3SD range by MEASURE Reagent	(ID-MS/SRM917)
LDH	**145**	**U/L**	**4.8**	**130 - 159**	**JSCC at 37℃ / Hitachi-7180**	JCCRM001d
	2.41	µkat/L	0.080	2.17 - 2.66	±3SD range by MEASURE Reagent	
LDH IFCC	**149**	**U/L**	**5.0**	**134 - 164**	**IFCC at 37°C / Hitachi-7180**	JCCRM001d
	2.49	µkat/L	0.083	2.24 - 2.74	±3SD range by MEASURE Reagent	
Protein,total	**63.4**	**g/L**	**2.11**	**57.1 - 69.7**	**Modified Biuret / Hitachi-7180**	JCCRM613
	6.34	g/dL	0.211	5.71 - 6.97	±3SD range by MEASURE Reagent	(srm927)
Trglyceride	**0.72**	**mmol/L**	**0.024**	**0.65 - 0.79**	**GPO/PAP**	JCCRM223
	63.3	mg/dL	2.11	57.0 - 69.6	±3SD range by MEASURE Reagent	(ID-MS)
(TG-T)	**1.09**	**mmol/L**	**0.036**	**0.98 - 1.20**	**GPO/PAP**	JCCRM223
	95.3	mg/dL	3.18	85.8 - 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**	**µmol/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 : ± 3SD

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(Other Method)

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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	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
Theophyline	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		

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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,