MEASURE Human Lyo L-2
for MESURE Reagent

Lot. 215ACJ (Blue Cap)

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

Component	Analytical value		1SD	Acceptable range			Method/Instrument	Traceability
Albumin	**63.1**	**g/L**	**2.10**	**56.8**	-	**69.4**	**BCG / Hitachi-7180**	JCCRM613
	6.31	g/dL	0.210	5.68	-	6.94	±3SD range by MEASURE Reagent	(ERM DA470)
ALT	**150**	**U/L**	**5.00**	**135**	-	**165**	**JSCC at 37℃ (IFCC w/o PalP) / Hitachi-7180**	JCCRM001d
	2.51	µkat/L	0.084	2.25	-	2.76	±3SD range by MEASURE Reagent	
ALP	**358**	**U/L**	**17.9**	**305**	-	**412**	**IFCC at 37℃ / Hitachi-7180**	JCCRM001d (IFCC)
	5.99	µkat/L	0.299	5.09	-	6.88	±3SD range by MEASURE Reagent	
ALP IFCC	**320**	**U/L**	**16.0**	**272**	-	**368**	**IFCC at 37℃ / Hitachi-7180**	JCCRM001d (IFCC)
	5.34	µkat/L	0.267	4.54	-	6.15	±3SD range by MEASURE Reagent	
Amylase, total	**399**	**U/L**	**19.95**	**339**	-	**459**	**IFCC at 37℃ / Hitachi-7180**	JCCRM001d
	6.66	µkat/L	0.333	5.66	-	7.66	±3SD range by MEASURE Reagent	
AST	**229**	**U/L**	**7.63**	**206**	-	**252**	**JSCC at 37℃ (IFCC w/o PalP) / Hitachi-7180**	JCCRM001d
	3.82	µkat/L	0.127	3.44	-	4.21	±3SD range by MEASURE Reagent	
Bile Acid	**110**	**µmol/L**	**11.00**	**77.0**	-	**143**	**Enzymatic (3-α-HDS) / Hitachi-7180**	Gravimetry
	42.7	mg/L	4.274	29.9	-	55.6	±3SD range by MEASURE Reagent	
Bilirubin, direct	**39.5**	**µmol/L**	**2.633**	**31.6**	-	**47.4**	**Enzymatic / Hitachi-7180**	NIST
	2.31	mg/dL	0.132	1.85	-	2.77	±3SD range by MEASURE Reagent	
Bilirubin, total	**72.0**	**µmol/L**	**2.40**	**64.8**	-	**79.2**	**Enzymatic / Hitachi-7180**	NIST
	4.21	mg/dL	0.140	3.79	-	4.63	±3SD range by MEASURE Reagent	
Cholesterol, total	**6.22**	**mmol/L**	**0.207**	**5.59**	-	**6.84**	**CHOD-PAP / Hitachi-7180**	JCCRM223
	240	mg/dL	8.0	216	-	264	±3SD range by MEASURE Reagent	(SRM1951a)
HDL Cholesterol (*)	**1.12**	**mmol/L**	**0.075**	**0.90**	-	**1.35**	**Direct enzymatic colorimetry / Hitachi-7180**	JCCRM223
	43.3	mg/dL	2.89	34.6	-	52.0	±3SD range by MEASURE Reagent	(SRM1951a)
LDL Cholesterol	**3.68**	**mmol/L**	**0.184**	**3.13**	-	**4.23**	**Direct enzymatic colorimetry / Hitachi7180**	JCCRM223
	142	mg/dL	7.10	121	-	163	±3SD range by MEASURE Reagent	(SRM1951a)
CK	**307**	**U/L**	**15.35**	**261**	-	**353**	**JSCC at 37℃ / Hitachi-7180**	JCCRM001d
	5.13	µkat/L	0.256	4.36	-	5.90	±3SD range by MEASURE Reagent	
CK-MB	**68.1**	**U/L**	**9.08**	**40.9**	-	**95.3**	**Immunological UV / Hitachi-7180**	Internal SOP
	1.14	µkat/L	0.152	0.68	-	1.59	±3SD range by MEASURE Reagent	
Creatinine	**276**	**µmol/L**	**11.03**	**243**	-	**309**	**Enzymatic / Hitachi-7180**	JCCRM521
	3.12	mg/dL	0.125	2.75	-	3.49	±3SD range by MEASURE Reagent	(ID-MS)
GGT	**150**	**U/L**	**6.00**	**132**	-	**168**	**JSCC at 37℃ / Hitachi-7180**	JCCRM001d
	2.51	µkat/L	0.301	2.20	-	2.81	±3SD range by MEASURE Reagent	
Glucose	**10.8**	**mmol/L**	**0.359**	**9.69**	-	11.8	**HDAOS-POD / Hitachi-7180**	JCCRM521
	194	mg/dL	6.47	175	-	213	±3SD range by MEASURE Reagent	(ID-MS/SRM917)
LDH	**332**	**U/L**	**11.1**	**299**	-	**365**	**JSCC at 37℃ / Hitachi-7180**	JCCRM001d
	5.54	µkat/L	0.185	4.99	-	6.09	±3SD range by MEASURE Reagent	
LDH IFCC	**342**	**U/L**	**11.4**	**308**	-	**376**	**IFCC at 37°C / Hitachi-7180**	JCCRM001d
	5.71	µkat/L	0.190	5.14	-	6.28	±3SD range by MEASURE Reagent	
Protein,total	**101**	**g/L**	**3.37**	**90.9**	-	**111**	**Modified Biuret / Hitachi-7180**	JCCRM613
	10.1	g/dL	0.337	9.09	-	11.1	±3SD range by MEASURE Reagent	(srm927)
Trglyceride	**1.01**	**mmol/L**	**0.034**	**0.91**	-	**1.11**	**GPO/PAP**	JCCRM223
	88.4	mg/dL	2.95	79.6	-	97	±3SD range by MEASURE Reagent	(ID-MS)
(TG-T)	**5.02**	**mmol/L**	**0.167**	**4.51**	-	**5.52**	**GPO/PAP**	JCCRM223
	440	mg/dL	14.67	396	-	484	±3SD range by MEASURE Reagent	(ID-MS)
Urea Nitrogen	**13.2**	**mmol/L**	**0.440**	**11.9**	-	**14.5**	**Urease-UV / Hitachi-7180**	JCCRM521
	36.9	mg/dL	1.23	33.2	-	40.6	±3SD range by MEASURE Reagent	(id-ms/srm912)
Uric acid	**702**	**µmol/L**	**23.4**	**632**	-	**772**	**Uricase-POD / Hitachi-7180**	JCCRM521
	11.8	mg/dL	0.393	10.6	-	13.0	±3SD range by MEASURE Reagent	(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 phosphomoplybdate	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
Theophyline	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

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
	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.