

MEASURE Human Lyo L-2
for MEASURE Reagent

Lot. 216AEL

(Blue Cap)

2°C~8°C EXP. 2027.06.

Component	Analytical value		1SD	Acceptable range		Method/Instrument	Traceability
Albumin	59.4	g/L	1.98	53.5	- 65.3	BCG / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM613 (ERM DA470)
	5.94	g/dL	0.198	5.35	- 6.53		
ALT	148	U/L	4.93	133	- 163	JSCC at 37°C (IFCC w/o PaP) / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
	2.47	µkat/L	0.082	2.22	- 2.72		
ALP IFCC	285	U/L	14.3	242	- 328	IFCC at 37°C / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d (IFCC)
	4.76	µkat/L	0.238	4.05	- 5.47		
Amylase, total	382	U/L	19.10	325	- 439	IFCC at 37°C / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
	6.38	µkat/L	0.319	5.42	- 7.34		
AST	230	U/L	7.67	207	- 253	JSCC at 37°C (IFCC w/o PaP) / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
	3.84	µkat/L	0.128	3.46	- 4.23		
Bile Acid	116	µmol/L	11.60	81.2	- 151	Enzymatic (3-α-HDS) / Hitachi-7180 ±3SD range by MEASURE Reagent	Gravimetry
	45.1	mg/L	4.507	31.5	- 58.6		
Bilirubin, direct	38.3	µmol/L	2.554	30.6	- 46.0	Enzymatic / Hitachi-7180 ±3SD range by MEASURE Reagent	NIST
	2.24	mg/dL	0.132	1.79	- 2.69		
Bilirubin, total	75.4	µmol/L	2.51	67.9	- 83.0	Enzymatic / Hitachi-7180 ±3SD range by MEASURE Reagent	NIST
	4.41	mg/dL	0.147	3.97	- 4.85		
Cholesterol, total	6.29	mmol/L	0.210	5.66	- 6.92	CHOD-PAP / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM223 (SRM1951a)
	243	mg/dL	8.1	219	- 267		
HDL Cholesterol ^(*)	2.12	mmol/L	0.141	1.70	- 2.55	Direct enzymatic colorimetry / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM223 (SRM1951a)
	81.9	mg/dL	5.46	65.5	- 98.3		
LDL Cholesterol	3.81	mmol/L	0.190	3.24	- 4.38	Direct enzymatic colorimetry / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM223 (SRM1951a)
	147	mg/dL	7.35	125	- 169		
CK	325	U/L	16.25	276	- 374	JSCC at 37°C / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
	5.43	µkat/L	0.271	4.61	- 6.24		
CK-MB	74.8	U/L	9.97	44.9	- 104.7	Immunological UV / Hitachi-7180 ±3SD range by MEASURE Reagent	Internal SOP
	1.25	µkat/L	0.167	0.75	- 1.75		
Creatinine	272	µmol/L	10.89	240	- 305	Enzymatic / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM521 (ID-MS)
	3.08	mg/dL	0.123	2.71	- 3.45		
GGT	160	U/L	6.40	141	- 179	JSCC at 37°C / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
	2.67	µkat/L	0.321	2.35	- 2.99		
Glucose	10.5	mmol/L	0.350	9.44	- 11.5	HK/G6P-DH / Hitachi-7180 HDAOS-POD / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM521 (ID-MS/SRM917)
	189	mg/dL	6.30	170	- 208		
LDH IFCC	344	U/L	11.5	310	- 378	IFCC at 37°C / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM001d
	5.74	µkat/L	0.191	5.17	- 6.32		
Protein, total	95.2	g/L	3.17	85.7	- 105	Modified Biuret / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM613 (srm927)
	9.52	g/dL	0.317	8.57	- 10.5		
Trglyceride	1.23	mmol/L	0.041	1.11	- 1.35	GPO/PAP ±3SD range by MEASURE Reagent	JCCRM223 (ID-MS)
	108.0	mg/dL	3.60	97.2	- 119		
(TG-T)	4.87	mmol/L	0.162	4.38	- 5.35	GPO/PAP ±3SD range by MEASURE Reagent	JCCRM223 (ID-MS)
	427	mg/dL	14.23	384	- 470		
Urea Nitrogen	13.3	mmol/L	0.443	12.0	- 14.6	Urease-UV / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM521 (id-ms/srm912)
	37.1	mg/dL	1.24	33.4	- 40.8		
Uric acid	690	µmol/L	23.0	621	- 759	Uricase-POD / Hitachi-7180 ±3SD range by MEASURE Reagent	JCCRM521 (ID-MS)
	11.6	mg/dL	0.387	10.4	- 12.8		

Acceptable range : ± 3SD HDL Cholesyrol value is Provisional value

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-2**(Other Method)****Lot. 216AEL****(Blue Cap)**

2°C ~ 8°C

EXP. 2027.06.

Component	Analytical value	U	Acceptable range	Method/Instrument	Traceability
ALT	155 U/L	17	138 - 172	IFCC 37°C with PaIP	IFCC
	2.59 μ kat/L	0.28	2.30 - 2.87		
Albumin	56.7 g/L	4.8	51.9 - 61.5	BCG	CRM470
	5.67 g/dL	0.38	5.29 - 6.05		
ALP	300 U/L	27	273 - 327	IFCC at 37°C	IFCC
	5.01 μ kat/L	0.45	4.56 - 5.46		
Amylase, total	372 U/L	25	347 - 397	IFCC at 37°C	IFCC
	6.21 μ kat/L	0.42	5.79 - 6.63		
Amylase, pancreas	191 U/L	15	176 - 206	Enzymatic colorimetry 37°C	
	3.19 μ kat/L	0.25	2.94 - 3.44		
AST	230 U/L	20	210 - 250	IFCC 37°C with PaIP	IFCC
	3.84 μ kat/L	0.33	3.51 - 4.18		
Bilirubin, direct	16.0 μ mol/L	1.6	14.4 - 17.6	Diazo	
	0.94 mg/dL	0.09	0.84 - 1.03		
Bilirubin, total	70.2 μ mol/L	8.1	62.1 - 78.3	DPD	Doumas method
	4.11 mg/dL	0.47	3.63 - 4.58		
Calucium	3.15 mmol/L	0.15	3.00 - 3.30	NM-BAPTA	SRM909b
	12.6 mg/dL	0.60	12.02 - 13.23		
Chloride	126 mmol/L	6	120 - 132	Indirect ISE	Gravimetry
Cholesterol, total	6.03 mmol/L	0.47	5.56 - 6.50	CHOD/PAP	ID-MS
	233 mg/dL	18	215 - 251		
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	3.45 mmol/L	0.34	3.11 - 3.79	Direct enzymatic colorimetry	SRM1951a
	133 mg/dL	13	120 - 147		
CK	329 U/L	44	285 - 373	IFCC at 37°C	IFCC
	5.49 μ kat/L	0.73	4.76 - 6.23		
CK-MB	60.0 U/L	13	47.0 - 73.0	Immunological UV	ERM-AD455/IFCC
	1.00 μ kat/L	0.22	0.78 - 1.22		
Copper	30.7 μ mol/L	3	27.7 - 33.7	ICP-MS	SRM 3114
Creatinine	255 μ mol/L	20	235 - 275	Enzymatic colorimetry	ID-MS
	2.88 mg/dL	0.23	2.66 - 3.11		
GGT	160 U/L	10	150 - 170	IFCC at 37°C	IFCC
	2.67 μ kat/L	0.17	2.51 - 2.84		
GLDH	10.3 U/L	1.0	9.30 - 11.3	DGKC 37°C	
	0.17 μ kat/L	0.02	0.16 - 0.19		
Glucose	10.6 mmol/L	0.9	9.70 - 11.5	HK/G6P-DH	ID-MS
	191 mg/dL	16	175 - 207		
Iron	37.1 μ mol/L	2.7	34.4 - 39.8	Ascorbate/FerroZine	SRM937
	207 μ g/dL	15.1	192 - 222		
Lactate	6.03 mmol/L	0.4	5.63 - 6.43	LOD/POD	Primery reference material
	54.3 mg/dL	3.6	50.7 - 57.9		
LDH	329 U/L	40	289 - 369	IFCC at 37°C	IFCC
	5.49 μ kat/L	0.67	4.83 - 6.16		
Lipase	97.9 U/L	11	86.9 - 109	Enzymatic colorimetry 37°C	Roche reagent manual measurement
	1.63 μ kat/L	0.18	1.45 - 1.82		
Lithium	2.00 mmol/L	0.05	1.95 - 2.05	Colorimetry	
	1.39 mg/dL	0.03	1.35 - 1.42		
Magnesium	1.48 mmol/L	0.11	1.37 - 1.59	Xylidyl-blue	Gravimetry
	3.60 mg/dL	0.27	3.33 - 3.86		
Phosphorus	3.01 mmol/L	0.17	2.84 - 3.18	Ammonium phosphomolybdate	Primary reference material
	9.32 mg/dL	0.53	8.80 - 9.85		
Potassium	5.97 mmol/L	0.34	5.63 - 6.31	Indirect ISE	Gravimetry
Protein total	90.3 g/L	8	82.3 - 98	Biuret	SRM927c
	9.03 g/dL	0.8	8.23 - 9.83		
Sodium	155 mmol/L	6	149 - 161	Indirect ISE	Gravimetry
Theophylline	127 μ mol/L			KIMS	Gravimetry
Total Bile Acid	120 μ mol/L	21	99 - 141	Enzymatic endpoint	
	46.8 mg/L	8.19	38.6 - 55.0		
Trglyceride	4.57 mmol/L	0.4	4.17 - 4.97	GPO/PAP	ID-MS
	405 mg/dL	35	369 - 440		

MEASURE Human Lyo L-2**(Other Method)****Lot. 216AEL****(Blue Cap)**

2°C ~ 8°C

EXP. 2027.06.

Component	Analytical value	U	Acceptable range	Method/Instrument	Traceability
UIBC	45.4 $\mu\text{mol/L}$	5.8	39.6 - 51.2	FeroZine®	Primary reference material
	253 $\mu\text{g/dL}$	32	221 - 286		
Urea	13.0 mmol/L	1.2	11.8 - 14.2	Urease/GLZDH	SRM909b
	36.4 mg/dL	3.4	33.1 - 39.8		
Uric acid	660 $\mu\text{mol/L}$	62	598 - 722	Uricase/POD	ID-MS
	11.1 mg/dL	1.04	10.1 - 12.1		
Zinc	39.7 $\mu\text{mol/L}$	2.1	37.6 - 41.8	ICP-MS	SRM 3168a
	259 $\mu\text{g/dL}$	14	246 - 273		

* (u) : uncertainty Acceptable range : $\pm 3\text{SD}$

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