

LIQUID CHEMISTRY PREMIUM PLUS - LEVEL 2 (LIQ CHEM PREMIUM PLUS 2)

** TYPICAL VALUES **

Cat. No. LUN5094 **Size:** 12 x 10 ml

INTENDED USE

This product is intended for *in vitro* diagnostic use, as an unassayed control to monitor laboratory precision on clinical chemistry systems.

DEVICE DESCRIPTION

The unassayed chemistry controls are supplied at 3 levels, level 1, 2 and 3.

SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

Human source material, from which this product has been derived, has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg), and Hepatitis C Virus (HCV) antibody, and found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests.

However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

Health and Safety Data Sheets are available on request.

STORAGE AND STABILITY

OPENED: Store refrigerated (+2°C to +8°C). Thawed serum is stable for 7 days at +2°C to +8°C, with the following exceptions: Troponin T is stable for 3 days at +2°C to +8°C. Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

UNOPENED: Store frozen at -20°C to -70°C. Stable to expiration date printed on individual vials (see Limitations).

LIMITATIONS

For Total & Prostatic Acid Phosphatase, the material should be stabilised by adding 1 drop (25 µl - 30 µl) of 0.7M Acetic acid solution to 1 ml of the serum after thawing. After stabilisation, Total & Prostatic Acid Phosphatase is stable for 7 days at +2°C to +8°C. Bilirubin in the serum is light sensitive and it is recommended that the serum be stored in the dark.

ALT, Total Acid Phosphatase, Alkaline Phosphatase, Total and Direct Bilirubin values may gradually decrease during the product's shelf life.

Bacterial contamination of the thawed serum will cause reductions in the stability of many components.

The control should not be used as a calibration material.

PREPARATION

1. Allow the frozen control to thaw at room temperature (+15°C to +25°C) until completely thawed. Swirl the contents to ensure homogeneity.
2. Refer to the Control section of the individual analyser application.
3. Refrigerate any unused material. Prior to reuse, mix contents thoroughly.

MATERIALS PROVIDED

Liquid Chemistry Premium Plus - Level 2 12 x 10 ml

MATERIALS REQUIRED BUT NOT PROVIDED

Not applicable.

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Analyte	unit	Target	methods
Albumin (electrophoresis)	%	47.6	Electrophoresis
alpha-1-globulin (electrophoresis)	%	15.1	Electrophoresis
alpha-2-globulin (electrophoresis)	%	8.3	Electrophoresis
beta-globulin (electrophoresis)	%	11.6	Electrophoresis
gamma-globulin (electrophoresis)	%	17.4	Electrophoresis
alpha-HBDH	U/l	83	Phosphate buffer DGKC 37°C
	U/l	63	Phosphate buffer DGKC 30°C
	U/l	47	Phosphate buffer DGKC 25°C
Acid Phosphatase (Prostatic)	U/l	15.1	1-Naphthyl Phosphate substrate Kinetic 37°C
Acid Phosphatase (Total)	U/l	17.2	1-Naphthyl Phosphate substrate Kinetic 37°C
Albumin	g/l	36.0	Bromocresol Green
	g/dl	3.60	
Alkaline Phosphatase	U/l	193	Diethanolamine buffer DEA 37°C
	U/l	150	Diethanolamine buffer DEA 30°C
	U/l	123	Diethanolamine buffer DEA 25°C
Alpha-1-Acid Glycoprotein	g/l	0.51	Immunoturbidimetric
Alpha-1-Antitrypsin	g/l	0.99	Immunoturbidimetric
Alphafoetoprotein	KIU/l = IU/ml	2.24	Chemiluminescence
	ng/ml	2.71	
ALT (GPT)	U/l	92	Tris buffer without P5P 37°C
	U/l	68	Tris buffer without P5P 30°C
	U/l	52	Tris buffer without P5P 25°C
Amikacin	µmol/l	20.8	Chemiluminescence
	µg/ml	12.2	
Amylase Pancreatic	U/l	123	Randox EPS Liquid 37°C
Amylase Total	U/l	149	Randox EPS Liquid 37°C
Apolipoprotein A-1	g/l	1.16	Immunoturbidimetric
	mg/dl	116	
Apolipoprotein B	g/l	0.64	Immunoturbidimetric
	mg/dl	64.0	
AST (GOT)	U/l	113	Tris buffer without P5P 37°C
	U/l	76	Tris buffer without P5P 30°C
	U/l	54	Tris buffer without P5P 25°C
Beta-2-microglobulin	µg/ml = mg/l	3.29	Immunoturbidimetric
Bicarbonate	mmol/l	21.2	Enzymatic
Bile Acids	µmol/l	29.1	5th Generation Colorimetric
Bilirubin Direct	µmol/l	20.6	Diazo with Sulphanilic Acid
	mg/dl	1.21	
Bilirubin Total	µmol/l	55.0	Diazo with Sulphanilic Acid
	mg/dl	3.22	
C-Reactive Protein	mg/l	17.6	Immunoturbidimetric

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Analyte	unit	Target	methods
Caeruloplasmin	g/l	0.306	Immunoturbidimetric
Caffeine	µmol/l	33.0	Immunoturbidimetric
	µg/ml	6.41	
Calcium	mmol/l	2.30	Cresolphthalein complexone
	mg/dl	9.22	
	mmol/l	1.15	Ionised calcium
	mg/dl	4.61	
Carbamazepine	µmol/l	35.6	Immunoturbidimetric
	µg/ml	8.42	
Carcinoembryonic Antigen (CEA)	ng/ml = µg/l	1.00	Chemiluminescence
Chloride	mmol/l	103	ISE indirect
Cholesterol	mmol/l	4.88	Cholesterol Oxidase
	mg/dl	188	
Cholinesterase	U/l	6084	Colorimetric 37°C
CK Total	U/l	233	Phosphate buffer DGKC 37°C
	U/l	146	Phosphate buffer DGKC 30°C
	U/l	99	Phosphate buffer DGKC 25°C
Complement C3	g/l	1.30	Immunoturbidimetric
Complement C4	g/l	0.21	Immunoturbidimetric
Copper	µmol/l	18.8	Colorimetric
	µg/dl	120	
Cortisol	nmol/l	510	Chemiluminescence
	µg/dl	18.4	
Creatinine	µmol/l	138	Alkaline picrate no deproteinization
	mg/dl	1.56	
D-3-Hydroxybutyrate	mmol/l	0.38	Enzymatic
DHEA-S	µmol/l	14.6	Chemiluminescence
Digoxin	nmol/l	2.09	Immunoturbidimetric
	ng/ml	1.63	
Ethanol	mg/dl	80.3	Chemiluminescence
Ferritin	ng/ml = µg/l	47.9	Abbott AXSYM
Folate	nmol/l	9.75	Competitive Protein Binding Assay
	ng/ml	4.30	
Free T3	pmol/l	6.56	Chemiluminescence
	ng/dl	0.43	
	pg/ml	4.27	
Free Thyroxine (FT4)	pmol/l	20.3	Chemiluminescence
	pg/ml	15.8	
FSH	mU/ml	13.7	Chemiluminescence
Gentamicin	µmol/l	11.2	Immunoturbidimetric
	µg/ml	5.35	
gamma-GT	U/l	78	Gamma glutamyl.-3-carboxy-4-nitroanilide 37°C
	U/l	61	Gamma glutamyl.-3-carboxy-4-nitroanilide 30°C
	U/l	48	Gamma glutamyl.-3-carboxy-4-nitroanilide 25°C

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GLDH	U/l	24	DGKC 37°C
	U/l	19	DGKC 30°C
	U/l	15	DGKC 25°C
Glucose	mmol/l	7.16	Glucose oxidase
	mg/dl	129	
Growth Hormone (GH)	µU/ml	2.43	Chemiluminescence
Haptoglobin	g/l	0.83	Immunoturbidimetric
HDL - Cholesterol	mmol/l	2.24	Direct Clearance Method
	mg/dl	86.5	
Immunoglobulin A	g/l	1.92	Immunoturbidimetric
Immunoglobulin E	KIU/l = IU/ml	178	Immunoturbidimetric
Immunoglobulin G	g/l	12.1	Immunoturbidimetric
Immunoglobulin M	g/l	0.86	Immunoturbidimetric
Iron	µmol/l	27.6	Colorimetric without ppt.
	µg/dl	154	
Lactate	mmol/l	1.39	Enzymatic Colorimetric
	mg/dl	12.5	
LAP	U/l	26	NAGEL 37°C
LD (LDH)	U/l	229	Phosphate buffer DGKC 37°C
	U/l	165	Phosphate buffer DGKC 30°C
	U/l	116	Phosphate buffer DGKC 25°C
LDL - Cholesterol	mmol/l	2.29	Direct Clearance Method
	mg/dl	88.4	
Lipase	U/l	60	Randox Colorimetric 37°C
Lipoprotein (a)	mg/dl	8.13	Immunoturbidimetric
	nmol/L	18.6	
Lithium	mmol/l	0.81	Colorimetric
	mg/dl	0.56	
Luteinising Hormone (LH)	mU/ml	12.8	Chemiluminescence
Magnesium	mmol/l	0.91	Xylidyl Blue
	mg/dl	2.21	
Myoglobin	ng/ml	127	Immunoturbidimetric
Osmolality	mmol/kg	717	Freezing point depression
Paracetamol	mmol/l	0.27	Polarisation Fluoroimmunoassay
	mg/l	40.5	
Phenobarbital	µmol/l	113	Immunoturbidimetric
	µg/ml	26.1	
Phenytoin	µmol/l	39.8	Immunoturbidimetric
	µg/ml	10.0	
Phosphate Inorganic	mmol/l	1.27	Phosphomolybdate UV
	mg/dl	3.94	

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Analyte	unit	Target	methods
Potassium	mmol/l	4.13	ISE indirect
Prealbumin	g/l	0.21	Immunoturbidimetric
Progesterone	nmol/l	27.1	Chemiluminescence
	ng/ml	8.48	
Prolactin	µU/ml	267	Chemiluminescence
Protein Total	g/l	66.8	Biuret reaction end point
	g/dl	6.68	
Salicylate	mmol/l	1.49	Colorimetric Trinder
	mg/dl	20.6	
Sodium	mmol/l	147	ISE indirect
T Uptake	%U	35.0	Siemens Immulite 1000
Testosterone	nmol/l	11.1	Chemiluminescence
	ng/ml	3.20	Chemiluminescence
	ng/dl	320	Chemiluminescence
Theophylline	µmol/l	70.8	Immunoturbidimetric
	µg/ml	12.8	
Thyroid Stimulating Hormone	µU/ml = mIU/l	4.23	Chemiluminescence
Thyroxine (T4)	nmol/l	95.1	Chemiluminescence
	µg/dl	7.42	Chemiluminescence
	ng/ml	74.2	Chemiluminescence
TIBC	µmol/l	51.9	FE+UIBC(saturation with iron)
	µg/dl	290	
Total Beta hCG	mU/ml	63.4	Chemiluminescence
Transferrin	g/l	2.28	Immunoturbidimetric
Triglycerides	mmol/l	2.38	Enzymatic Colorimetric
	mg/dl	211	
Triiodothyronine (T3)	nmol/l	1.49	Chemiluminescence
	ng/ml	0.97	Chemiluminescence
	ng/dl	97.0	Chemiluminescence
Troponin T	pg/ml	370	Chemiluminescence
UIBC	µmol/l	24.3	TIBC - FE
	µg/dl	136	
Urea	mmol/l	9.61	Enzymatic
	mg/dl	57.8	
	mmol/l	9.61	BUN
Uric Acid (Urate)	mmol/l	0.24	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	4.05	
Valproic Acid	µmol/l	269	Immunoturbidimetric
	µg/ml	38.8	
Vancomycin	µmol/l	6.80	Polarisation Fluoroimmunoassay
	µg/ml	10.1	
Vitamin B12	pmol/l	502	Competitive Protein Binding Assay
	pg/ml	680	

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Zinc	µmol/l	26.9	Colorimetric
	µg/dl	176	