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

** TYPICAL VALUES **

Cat. No. LUN 5048 Size: 12 x 5 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 2 levels, level 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 is stored in the dark.
ALT, Total Acid Phosphatase, Alkaline Phosphatase, Total and Direct Bilirubin values may gradually decrease during the products 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 - Level 2 12 x 5 ml

MATERIALS REQUIRED BUT NOT PROVIDED
N/A

Revised 06 Nov 13 rw

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**** TYPICAL VALUES ****

Analyte	unit	target	methods
Albumin (electrophoresis)	%	63.6	Electrophoresis
alpha-1-globulin (electrophoresis)	%	3.5	Electrophoresis
alpha-2-globulin (electrophoresis)	%	8.0	Electrophoresis
beta-globulin (electrophoresis)	%	12.4	Electrophoresis
gamma-globulin (electrophoresis)	%	12.5	Electrophoresis
alpha-HBDH	U/l	212	Phosphate buffer DGKC 37°C
	U/l	160	Phosphate buffer DGKC 30°C
	U/l	120	Phosphate buffer DGKC 25°C
Acid Phosphatase (Prostatic)	U/l	8.17	1-Naphthyl Phosphate substrate Kinetic 37°C
Acid Phosphatase (Total)	U/l	16.1	1-Naphthyl Phosphate substrate Kinetic 37°C
Albumin	g/l	39.8	Bromocresol Green
	g/dl	3.98	
Alkaline Phosphatase	U/l	301	Diethanolamine buffer DEA 37°C
	U/l	234	Diethanolamine buffer DEA 30°C
	U/l	192	Diethanolamine buffer DEA 25°C
Alpha-1-Acid Glycoprotein	g/l	0.47	Immunoturbidimetric
Alpha-1-Antitrypsin	g/l	1.01	Immunoturbidimetric
Alphafoetoprotein	KIU/l = IU/ml	1.90	Chemiluminescence
	ng/ml	2.30	
ALT (GPT)	U/l	38	Tris buffer no P5P 37°C
	U/l	28	Tris buffer no P5P 30°C
	U/l	21	Tris buffer no P5P 25°C
Amylase Pancreatic	U/l	89	Randox EPS Liquid 37°C
Amylase Total	U/l	110	Randox EPS Liquid 37°C
Apolipoprotein A-1	g/l	1.02	Immunoturbidimetric
	mg/dl	102	
Apolipoprotein B	g/l	0.63	Immunoturbidimetric
	mg/dl	63.0	
AST (GOT)	U/l	40	Tris buffer no P5P 37°C
	U/l	27	Tris buffer no P5P 30°C
	U/l	19	Tris buffer no P5P 25°C
Bicarbonate	mmol/l	23.8	Enzymatic
Bile Acids	µmol/l	35.0	5th Generation Colorimetric
Bilirubin Direct	µmol/l	21.9	Diazo with Sulphanilic Acid
	mg/dl	1.28	
Bilirubin Total	µmol/l	26.7	Diazo with Sulphanilic Acid
	mg/dl	1.56	
C-Reactive Protein	mg/l	2.87	Immunoturbidimetric
Caeruloplasmin	g/l	0.260	Nephelometric
Calcium	mmol/l	2.31	Cresolphthalein complexone
	mg/dl	9.26	

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**** TYPICAL VALUES ****

Analyte	unit	target	methods
Calcium	mmol/l	1.16	Ionised calcium
	mg/dl	4.65	
Carbamazepine	µmol/l	36.3	Immunoturbidimetric
	µg/ml	8.58	
Carcinoembryonic Antigen (CEA)	ng/ml = µg/l	1.10	Chemiluminescence
Chloride	mmol/l	94.1	ISE indirect
Cholesterol	mmol/l	4.12	Cholesterol Oxidase
	mg/dl	159	
Cholinesterase	U/l	5565	Colorimetric 37°C
CK Total	U/l	245	Phosphate buffer DGKC 37°C
	U/l	153	Phosphate buffer DGKC 30°C
	U/l	104	Phosphate buffer DGKC 25°C
Complement C3	g/l	0.91	Immunoturbidimetric
Complement C4	g/l	0.18	Immunoturbidimetric
Copper	µmol/l	17.0	Colorimetric
	µg/dl	108	
Cortisol	nmol/l	170	Radioimmunoassay
	µg/dl	6.12	
Creatinine	µmol/l	131	Alkaline picrate no deproteinization
	mg/dl	1.48	
D-3-Hydroxybutyrate	mmol/l	0.36	Enzymatic
Digoxin	nmol/l	1.97	Immunoturbidimetric
	ng/ml	1.54	
Ethanol	mg/dl	24.6	Enzymatic Colorimetric
Ferritin	ng/ml = µg/l	49.8	Abbott AXSYM
Folate	nmol/l	36.3	Chemiluminescence
	ng/ml	16.0	
Free T3	pmol/l	7.00	Chemiluminescence
	ng/dl	0.46	
	pg/ml	4.56	
Free Thyroxine (FT4)	pmol/l	14.0	Chemiluminescence
	pg/ml	10.9	
Gentamicin	µmol/l	7.09	Immunoturbidimetric
	µg/ml	3.39	
gamma-GT	U/l	64	Gamma glutamyl.-3-carboxy-4-nitroanilide 37°C
	U/l	50	Gamma glutamyl.-3-carboxy-4-nitroanilide 30°C
	U/l	39	Gamma glutamyl.-3-carboxy-4-nitroanilide 25°C
GLDH	U/l	17	DGKC 37°C
	U/l	13	DGKC 30°C
	U/l	11	DGKC 25°C
Glucose	mmol/l	5.70	Glucose oxidase
	mg/dl	103	

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Analyte	unit	target	methods
Haptoglobin	g/l	0.899	Immunoturbidimetric
HDL - Cholesterol	mmol/l	1.31	Direct Clearance Method
	mg/dl	50.6	
Immunoglobulin A	g/l	1.71	Immunoturbidimetric
Immunoglobulin E	KIU/l = IU/ml	64.9	Immunoturbidimetric
Immunoglobulin G	g/l	8.01	Immunoturbidimetric
Immunoglobulin M	g/l	0.64	Immunoturbidimetric
Iron	µmol/l	21.3	Colorimetric without ppt.
	µg/dl	119	
Lactate	mmol/l	1.40	Enzymatic Colorimetric
	mg/dl	12.6	
LAP	U/l	20	NAGEL 37°C
LD (LDH)	U/l	386	Phosphate buffer DGKC 37°C
	U/l	279	Phosphate buffer DGKC 30°C
	U/l	196	Phosphate buffer DGKC 25°C
LDL - Cholesterol	mmol/l	2.20	Direct Clearance Method
	mg/dl	84.9	
Lipase	U/l	74	Randox Colorimetric 37°C
Lipoprotein (a)	mg/dl	18.0	Immunoturbidimetric
	nmol/l	180	
Lithium	mmol/l	0.91	Colorimetric
	mg/dl	0.63	
Magnesium	mmol/l	0.98	Xylidyl Blue
	mg/dl	2.38	
Myoglobin	ng/ml	40.5	Immunoturbidimetric
Osmolality	mOsm/kg	758	Freezing point depression
Paracetamol	mmol/l	0.05	Immunoturbidimetric
	mg/l	7.01	
Phenobarbital	µmol/l	126	Immunoturbidimetric
	µg/ml	29.2	
Phenytoin	µmol/l	48.2	Immunoturbidimetric
	µg/ml	12.2	
Phosphate Inorganic	mmol/l	1.43	Phosphomolybdate UV
	mg/dl	4.43	
Potassium	mmol/l	4.00	ISE indirect
Prealbumin	g/l	0.24	Immunoturbidimetric
Prolactin	µU/ml	140	Chemiluminescence
Protein Total	g/l	60.6	Biuret reaction end point
	g/dl	6.06	
PSA Total	ng/ml = µg/l	7.00	Chemiluminescence
Salicylate	mmol/l	0.63	Colorimetric Trinder
	mg/dl	8.74	
Sodium	mmol/l	139	ISE indirect

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**** TYPICAL VALUES ****

Analyte	unit	target	methods
Theophylline	µmol/l	28.6	Immunoturbidimetric
	µg/ml	5.15	
Thyroid Stimulating Hormone	µU/ml = mIU/l	1.50	Chemiluminescence
Thyroxine (T4)	nmol/l	90.0	Chemiluminescence
	µg/dl	7.02	
TIBC	µmol/l	43.3	FE+UIBC(saturation with iron)
	µg/dl	242	
Total Beta hCG	mU/ml	23.0	Chemiluminescence
Transferrin	g/l	1.91	Immunoturbidimetric
Triglycerides	mmol/l	0.94	Enzymatic Colorimetric
	mg/dl	83.2	
Triiodothyronine (T3)	nmol/l	2.30	Chemiluminescence
	ng/ml	1.50	
Troponin T	µg/l	0.01	Chemiluminescence
UIBC	µmol/l	22.0	TIBC - FE
	µg/dl	123	
Urea	mmol/l	7.42	Enzymatic
	mg/dl	44.6	
	mmol/l	7.42	BUN
	mg/dl	20.8	
Uric Acid (Urate)	mmol/l	0.35	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	5.88	
Valproic Acid	µmol/l	547	Immunoturbidimetric
	µg/ml	78.9	
Vancomycin	µmol/l	9.42	Polarisation Fluoroimmunoassay
	µg/ml	14.0	
Vitamin B12	pmol/l	207	Chemiluminescence
	pg/ml	280	
Zinc	µmol/l	34.4	Colorimetric
	µg/dl	225	