

Artikel-Nr.: KG5049 Inhalt: 12 x 5 ml
****TYPISCHE WERTE****

INTENDED USE

Liquid Chemistry Premium is intended for in-vitro diagnostic use in the quality control of 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 to 8°C). Thawed serum is stable for 7 days at +2 to +8°C, with the following exceptions:

Folate and Vitamin B12 are stable for 5 days at +2 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 -80°C. Stable to expiration date printed on individual vials. (See limitations)

LIMITATIONS

For Total & Prostatic Acid Phosphatase the material should be stabilized by adding 1 drop (25-30µl) of 0.7M Acetic acid solution to 1ml of the serum after thawing. After stabilization Total & Prostatic Acid Phosphatase is stable for 7 days at +2 to +8°C.

Bilirubin in the serum is light sensitive and it is recommended that the serum be stored in the dark.

Total and Direct Bilirubin values will gradually decrease during the products shelf life.

Bacterial contamination of the reconstituted 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 (+18°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 3 12 x 5ml

MATERIALS REQUIRED BUT NOT PROVIDED

None

ASSIGNED VALUES

Approximate values are assigned from results obtained from internal testing conducted at BGT BioGenTechnologies GmbH.

LIQUID CHEMISTRY PREMIUM LEVEL 3

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****TYPISCHE WERTE****

Parameter	Einheit	Zielwert	Methoden
Albumin (electrophoresis)	%	58.2	Electrophoresis
alpha-1-globulin (electrophoresis)	%	6.0	Electrophoresis
alpha-2-globulin (electrophoresis)	%	8.6	Electrophoresis
beta-globulin (electrophoresis)	%	13.3	Electrophoresis
gamma-globulin (electrophoresis)	%	14.0	Electrophoresis
alpha-HBDH	U/l	408	Phosphate buffer DGKC 37°C
	U/l	308	Phosphate buffer DGKC 30°C
	U/l	231	Phosphate buffer DGKC 25°C
Acid Phosphatase (Prostatic)	U/l	26.3	1-Naphthyl Phosphate substrate Kinetic 37°C
Acid Phosphatase (Total)	U/l	42.8	1-Naphthyl Phosphate substrate Kinetic 37°C
Albumin	g/l	28.2	Bromocresol Green
	g/dl	2.82	
Alkaline Phosphatase	U/l	486	Diethanolamine buffer DEA 37°C
	U/l	379	Diethanolamine buffer DEA 30°C
	U/l	311	Diethanolamine buffer DEA 25°C
Alpha-1-Acid Glycoprotein	g/l	0.41	Immunoturbidimetric
Alpha-1-Antitrypsin	g/l	0.88	Immunoturbidimetric
Alphafoetoprotein	KIU/l = IU/ml	1.60	Chemiluminescence
	ng/ml	1.94	
ALT (GPT)	U/l	136	Tris buffer no P5P IFCC/SFBC 37°C
	U/l	101	Tris buffer no P5P IFCC/SFBC 30°C
	U/l	77	Tris buffer no P5P IFCC/SFBC 25°C
Amylase Pancreatic	U/l	269	Randox EPS Liquid 37°C
Amylase Total	U/l	296	Randox EPS Liquid 37°C
Apolipoprotein A-1	g/l	1.12	Immunoturbidimetric
	mg/dl	112	
Apolipoprotein B	g/l	0.58	Immunoturbidimetric
	mg/dl	58.0	
AST (GOT)	U/l	145	Tris buffer no P5P IFCC/SFBC 37°C
	U/l	98	Tris buffer no P5P IFCC/SFBC 30°C
	U/l	69	Tris buffer no P5P IFCC/SFBC 25°C
Bicarbonate	mmol/l	26.9	Enzymatic
Bile Acids	µmol/l	51.4	5th Generation Colorimetric
Bilirubin Direct	µmol/l	28.4	Diazo with Sulphanilic Acid
	mg/dl	1.66	
Bilirubin Total	µmol/l	80.7	Diazo with Sulphanilic Acid
	mg/dl	4.72	
C-Reactive Protein	mg/l	6.10	Immunoturbidimetric
Caeruloplasmin	g/l	0.235	Chemiluminescence
Calcium	mmol/l	1.47	Ionised calcium
	mg/dl	5.87L	

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Calcium	mmol/l	2.93	Cresolphthalein complexone
	mg/dl	11.7	
Carbamazepine	µmol/l	58.4	Immunoturbidimetric
	µg/ml	13.8	
Carcinoembryonic Antigen (CEA)	ng/ml = µg/l	1.00	Chemiluminescence
Chloride	mmol/l	110	ISE indirect
Cholesterol	mmol/l	7.45	Cholesterol Oxidase CDC
	mg/dl	288	
Cholinesterase	U/l	4882	Colorimetric 37°C
CK Total	U/l	534	Phosphate buffer DGKC 37°C
	U/l	334	Phosphate buffer DGKC 30°C
	U/l	227	Phosphate buffer DGKC 25°C
Complement C3	g/l	0.86	Immunoturbidimetric
Complement C4	g/l	0.16	Immunoturbidimetric
Copper	µmol/l	25.0	Colorimetric
	µg/dl	159	
Cortisol	nmol/l	150	Radioimmunoassay
	µg/dl	5.40	
Creatinine	µmol/l	300	Alkaline picrate no deproteinization
	mg/dl	3.39	
D-3-Hydroxybutyrate	mmol/l	1.03	Enzymatic
Digoxin	nmol/l	3.52	Immunoturbidimetric
	ng/ml	2.75	
Ethanol	mg/dl	212	Enzymatic Colorimetric
Ferritin	ng/ml = µg/l	46.4	Abbott AXSYM
Folate	nmol/l	22.7	Chemiluminescence
	ng/ml	10.0	
Free T3	pmol/l	12.0	Chemiluminescence
	ng/dl	0.78	
	pg/ml	7.81	
Free Thyroxine (FT4)	pmol/l	25.0	Chemiluminescence
	pg/ml	19.5	
Gentamicin	µmol/l	15.4	Immunoturbidimetric
	µg/ml	7.34	
gamma-GT	U/l	206	Gamma glutamyl.-3-carboxy-4-nitroanilide 37°C
	U/l	162	Gamma glutamyl.-3-carboxy-4-nitroanilide 30°C
	U/l	127	Gamma glutamyl.-3-carboxy-4-nitroanilide 25°C
GLDH	U/l	31	DGKC 37°C
	U/l	24	DGKC 30°C
	U/l	19	DGKC 25°C
Glucose	mmol/l	13.5	Glucose oxidase
	mg/dl	244	

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Parameter	Einheit	Zielwert	Methoden
Haptoglobin	g/l	73.7	Chemiluminescence
HDL - Cholesterol	mmol/l	3.37	Direct Clearance Method
	mg/dl	130	
Human Chorionic Gonadotrophin	mU/ml	450	Chemiluminescence
Immunoglobulin A	g/l	1.71	Immunoturbidimetric
Immunoglobulin E	KIU/l = IU/ml	59.2	Immunoturbidimetric
Immunoglobulin G	g/l	6.79	Immunoturbidimetric
Immunoglobulin M	g/l	0.95	Immunoturbidimetric
Iron	µmol/l	33.9	Colorimetric without ppt.
	µg/dl	190	
Lactate	mmol/l	4.94	Enzymatic Colorimetric
	mg/dl	44.5	
LAP	U/l	18	NAGEL 37°C
LD (LDH)	U/l	712	Phosphate buffer DGKC 37°C
	U/l	514	Phosphate buffer DGKC 30°C
	U/l	361	Phosphate buffer DGKC 25°C
LDL - Cholesterol	mmol/l	2.10	Direct Clearance Method
	mg/dl	81.1	
Lipase	U/l	112	Randox Colorimetric 37°C
Lipoprotein (a)	mg/dl	22.0	Immunoturbidimetric
	nmol/L	220	
Lithium	mmol/l	1.67	Colorimetric
	mg/dl	1.16	
Magnesium	mmol/l	1.63	Xylidyl Blue
	mg/dl	3.96	
Myoglobin	ng/ml	253	Immunoturbidimetric
Osmolality	mOsm/kg	751	Freezing point depression
Paracetamol	mmol/l	0.45	Polarisation Fluoroimmunoassay
	mg/l	68.4	
Phenobarbital	µmol/l	211	Immunoturbidimetric
	µg/ml	48.8	
Phenytoin	µmol/l	57.7	Immunoturbidimetric
	µg/ml	14.6	
Phosphate Inorganic	mmol/l	2.10	Phosphomolybdate UV
	mg/dl	6.51	
Potassium	mmol/l	5.98	ISE indirect
Prealbumin	g/l	0.18	Immunoturbidimetric
Prolactin	µU/ml	130	Chemiluminescence
Protein Total	g/l	46.3	Biuret reaction end point
	g/dl	4.63	
PSA Total	ng/ml = µg/l	15.0	Chemiluminescence
Salicylate	mmol/l	1.05	Colorimetric Trinder
	mg/dl	14.5	

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Sodium	mmol/l	154	ISE indirect
Theophylline	µmol/l	116	Immunoturbidimetric
	µg/ml	20.9	
Thyroid Stimulating Hormone	µU/ml = mIU/l	14.7	Chemiluminescence
Thyroxine (T4)	nmol/l	240	Chemiluminescence
	µg/dl	18.7	
TIBC	µmol/l	7.49	FE+UIBC(saturation with iron)
	µg/dl	41.9	
Transferrin	g/l	1.64	Immunoturbidimetric
Triglycerides	mmol/l	2.47	Enzymatic Colorimetric
	mg/dl	219	
Triiodothyronine (T3)	nmol/l	3.00	Chemiluminescence
	ng/ml	1.95	
Troponin I	ng/ml = µg/l	3.70	Chemiluminescence
Troponin T	µg/L	0.23	Chemiluminescence
Urea	mmol/l	17.4	Enzymatic
	mg/dl	105	
Uric Acid (Urate)	mmol/l	0.53	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	8.89	
Valproic Acid	µmol/l	825	Immunoturbidimetric
	µg/ml	119	
Vancomycin	µmol/l	17.0	Polarisation Fluoroimmunoassay
	µg/ml	25.3	
Vitamin B12	pmol/l	300	Chemiluminescence
	pg/ml	407	
Zinc	µmol/l	34.7	Colorimetric
	µg/dl	226	