

**Artikel-Nr.:** KG5067  
**Chargen.-B.:** 674UN

**Inhalt:** 5 ml  
**Verwendbar bis:** 2013-08

#### INTENDED USE

This product is intended for in vitro diagnostic use in the quality control of diagnostic assays. Chemistry Premium is for the control of accuracy.

#### DEVICE DESCRIPTION

Chemistry Premium is supplied at 2 levels, level 2 and 3. Target values and ranges are supplied for the analytes listed in the value section at both levels.

#### 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). Reconstituted serum is stable for 8 hours at +25°C or 7 days at +2°C to +8°C and 1 month when frozen once at -20°C (See Limitations).

#### LIMITATIONS

For Total & Prostatic Acid Phosphatase, the material should be stabilised by adding 1 drop (25 - 30 µl) of 0.7M Acetic acid solution to 1ml of the serum exactly 30 minutes after reconstitution. After stabilisation Total and Prostatic Acid Phosphatase is stable for 2 hours +25°C, 2 days at +2°C to +8°C and 1 month when frozen once at -20°C.

Alkaline Phosphatase levels in the reconstituted serum will rise over the stability period. It is recommended that the reconstituted serum be allowed to stand for 1 hour at +25°C before measurement.

Bilirubin in the serum is light sensitive and it is recommended that the serum be stored in the dark. Stored in the dark it is stable for 4 days at +2°C to +8°C. Do not store at +15°C to +25°C. Do not freeze.

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

Different lot numbers of this control should not be interchanged as the values assigned to the controls vary from lot to lot. The control should not be used as a calibration material.

UNOPENED: Store refrigerated (+2°C to +8°C). Stable to expiration date printed on individual vials.

#### PREPARATION FOR USE

Chemistry Premium is supplied lyophilised.

1. Carefully reconstitute each vial of lyophilised serum with exactly 5 ml of distilled water at +20°C to +25°C. Close the bottle and allow to stand for 30 minutes before use. Ensure contents are completely dissolved by swirling gently. Avoid formation of foam. Do not shake.
2. Refer to the control section of the individual analyser application.
3. Refrigerate any unused material. Prior to reuse, mix contents thoroughly.

#### MATERIALS PROVIDED

Chemistry Premium Level 2 5 ml

#### MATERIALS REQUIRED BUT NOT PROVIDED

Volumetric Pipette

#### ASSIGNED VALUES

Each batch of Chemistry Premium is assigned at BGT BioGenTechnologies GmbH with reference to an internal master calibrator which is traceable to international Reference Standards.

#### NOTES

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- (1) DGKC : German Society for Clinical Chemistry
- (2) IFCC : International Federation of Clinical Chemistry
- (3) SCE : Scandinavian Committee on Enzymes

## CHEMISTRY PREMIUM - LEVEL 2 (CHEM PREMIUM 2)

Ch.-B.: 674UN Art.-Nr.: KG5067

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Parameter	Einheit	Zielwert	Bereich		1SD	2SD	Methoden
			von	bis			
alpha-HBDH	U/l	205	162	248	21.50	43.00	Oxobutyrate < 10 mmol/l 37°C
	U/l	155	122	188	16.50	33.00	Oxobutyrate < 10 mmol/l 30°C
	U/l	116	92	140	12.00	24.00	Oxobutyrate < 10 mmol/l 25°C
Acid Phosphatase (Prostatic)	U/l	9.75	6.53	13.0	1.61	3.22	1-Naphthyl Phosphate substrate Kinetic 37°C
Acid Phosphatase (Total)	U/l	14.6	9.78	19.4	2.41	4.82	1-Naphthyl Phosphate substrate Kinetic 37°C
Albumin	g/l	41.3	35.1	47.5	3.10	6.20	Bromocresol Green
	g/dl	4.13	3.51	4.75	0.31	0.62	
Alkaline Phosphatase	U/l	276	235	317	20.50	41.00	Diethanolamine buffer DEA 37°C
	U/l	215	183	247	16.00	32.00	Diethanolamine buffer DEA 30°C
	U/l	176	150	202	13.00	26.00	Diethanolamine buffer DEA 25°C
ALT (GPT)	U/l	38	30	46	4.00	8.00	Tris buffer no P5P IFCC/SFBC 37°C
	U/l	28	22	34	3.00	6.00	Tris buffer no P5P IFCC/SFBC 30°C
	U/l	21	17	25	2.00	4.00	Tris buffer no P5P IFCC/SFBC 25°C
Amylase Pancreatic	U/l	70	60	80	5.00	10.00	Randox liquid pNPG7 37°C
Amylase Total	U/l	91	77	105	7.00	14.00	Randox liquid stable pNPG7 37°C
AST (GOT)	U/l	37	30	44	3.50	7.00	Tris buffer no P5P IFCC/SFBC 37°C
	U/l	25	20	30	2.50	5.00	Tris buffer no P5P IFCC/SFBC 30°C
	U/l	18	14	22	2.00	4.00	Tris buffer no P5P IFCC/SFBC 25°C
Bilirubin Direct	µmol/l	19.3	15.2	23.4	2.05	4.10	Diazo with Sulphanilic Acid
	mg/dl	1.13	0.889	1.37	0.12	0.24	
Bilirubin Total	µmol/l	28.3	22.4	34.2	2.95	5.90	Diazo with Sulphanilic Acid
	mg/dl	1.66	1.31	2.01	0.18	0.35	

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Parameter	Einheit	Zielwert	Bereich		1SD	2SD	Methoden
			von	bis			
Calcium	mmol/l	2.18	1.96	2.40	0.11	0.22	Cresolphthalein complexone
	mg/dl	8.74	7.86	9.62	0.44	0.88	
Chloride	mmol/l	99.8	91.8	108	4.00	8.00	ISE direct
Cholesterol	mmol/l	4.07	3.54	4.60	0.27	0.53	Cholesterol Oxidase CDC
	mg/dl	157	137	177	10.00	20.00	
Cholinesterase	U/l	4992	3994	5990	499.00	998.00	Colorimetric Butyrylthiocholine 37°C
CK Total	U/l	220	180	260	20.00	40.00	CK-NAC substrate start (DGKC) 37°C
	U/l	138	113	163	12.50	25.00	CK-NAC substrate start (DGKC) 30°C
	U/l	94	77	111	8.50	17.00	CK-NAC substrate start (DGKC) 25°C
Creatinine	µmol/l	129	106	152	11.50	23.00	Alkaline picrate no deproteinization
	mg/dl	1.46	1.20	1.72	0.13	0.26	
gamma-GT	U/l	56	48	64	4.00	8.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
	U/l	44	38	50	3.00	6.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 30°C
	U/l	35	30	40	2.50	5.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 25°C
GLDH	U/l	17	13	21	2.00	4.00	Triethanolamine buffer 50 mmol 37°C
	U/l	13	10	16	1.50	3.00	Triethanolamine buffer 50 mmol 30°C
	U/l	11	8	14	1.50	3.00	Triethanolamine buffer 50 mmol 25°C
Glucose	mmol/l	6.54	5.56	7.52	0.49	0.98	Glucose oxidase
	mg/dl	118	100	136	9.00	18.00	
Immunoglobulin A	g/l	1.51	1.13	1.89	0.19	0.38	Immunoturbidimetric
	mg/dl	151	113	189	19.00	38.00	
Immunoglobulin G	g/l	7.04	5.77	8.31	0.64	1.27	Immunoturbidimetric
	mg/dl	704	577	831	63.50	127.00	
Immunoglobulin M	g/l	0.93	0.74	1.12	0.09	0.19	Immunoturbidimetric
	mg/dl	93.0	74.4	112	9.30	18.60	

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Parameter	Einheit	Zielwert	von	bis	1SD	2SD	Methoden
Iron	µmol/l	19.6	16.1	23.1	1.75	3.50	Colorimetric without ppt.
	µg/dl	110	90.0	130	10.00	20.00	
Lactate	mmol/l	1.44	1.18	1.70	0.13	0.26	Enzymatic Colorimetric
	mg/dl	13.0	10.6	15.4	1.20	2.40	
LAP	U/l	16	14	18	1.00	2.00	NAGEL 37°C
LD (LDH)	U/l	385	327	443	29.00	58.00	P->L German Methoden 37°C
	U/l	278	236	320	21.00	42.00	P->L German Methoden 30°C
	U/l	195	166	224	14.50	29.00	P->L German Methoden 25°C
Lipase	U/l	45	36	54	4.50	9.00	Randox Colorimetric 37°C
Lithium	mmol/l	0.90	0.79	1.01	0.05	0.11	Spectrophotometric
	mg/dl	0.625	0.550	0.700	0.04	0.08	
Magnesium	mmol/l	0.91	0.80	1.02	0.05	0.11	Xylidyl Blue
	mg/dl	2.21	1.95	2.47	0.13	0.26	
Phosphate Inorganic	mmol/l	1.44	1.22	1.66	0.11	0.22	Phosphomolybdate UV
	mg/dl	4.46	3.78	5.14	0.34	0.68	
Potassium	mmol/l	4.10	3.77	4.43	0.17	0.33	ISE method - direct
Protein Total	g/l	58.6	46.9	70.3	5.85	11.70	Biuret reaction end point
	g/dl	5.86	4.69	7.03	0.59	1.17	
Sodium	mmol/l	152	144	160	4.00	8.00	ISE method - direct
TIBC	µmol/l	44.2	34.9	53.5	4.65	9.30	Randox Colorimetric
	µg/dl	247	195	299	26.00	52.00	
Transferrin	g/l	1.73	1.38	2.08	0.18	0.35	Immunoturbidimetric
	mg/dl	173	138	208	17.50	35.00	
Triglycerides	mmol/l	1.02	0.86	1.18	0.08	0.16	Lipase/GPO-PAP no correction
	mg/dl	90.3	75.8	105	7.25	14.50	

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Parameter	Einheit	Zielwert	von	bis	1SD	2SD	Methoden
UIBC	µmol/l	24.6	20.2	29.0	2.20	4.40	TIBC - FE
	µg/dl	138	113	163	12.50	25.00	
Urea	mmol/l	7.08	6.02	8.14	0.53	1.06	Urease kinetic
	mg/dl	42.6	36.2	49.0	3.20	6.40	
Uric Acid (Urate)	mmol/l	0.33	0.28	0.37	0.02	0.04	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	5.48	4.77	6.19	0.36	0.71	