

Artikel-Nr.: KG5068
Chargen-B: 478UE

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.
- 4.

MATERIALS PROVIDED

Chemistry Premium Level 3 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 3 (CHEM PREMIUM 3)

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Inhalt 5ml	Verw. bis: 2013-08	Bereich					
Parameter	Einheit	Zielwert	von	bis	1SD	2SD	Methoden
alpha-HBDH	U/l	403	318	488	42.50	85.00	Oxobutyrate < 10 mmol/l 37°C
	U/l	304	240	368	32.00	64.00	Oxobutyrate < 10 mmol/l 30°C
	U/l	228	180	276	24.00	48.00	Oxobutyrate < 10 mmol/l 25°C
Acid Phosphatase (Prostatic)	U/l	25.8	17.3	34.3	4.25	8.50	1-Naphthyl Phosphate substrate Kinetic 37°C
Acid Phosphatase (Total)	U/l	38.1	25.5	50.7	6.30	12.60	1-Naphthyl Phosphate substrate Kinetic 37°C
Albumin	g/l	30.3	25.8	34.8	2.25	4.50	Bromocresol Green
	g/dl	3.03	2.58	3.48	0.23	0.45	
Alkaline Phosphatase	U/l	541	460	622	40.50	81.00	Diethanolamine buffer DEA 37°C
	U/l	421	358	484	31.50	63.00	Diethanolamine buffer DEA 30°C
	U/l	346	294	398	26.00	52.00	Diethanolamine buffer DEA 25°C
ALT (GPT)	U/l	136	109	163	13.50	27.00	Tris buffer no P5P IFCC/SFBC 37°C
	U/l	101	81	121	10.00	20.00	Tris buffer no P5P IFCC/SFBC 30°C
	U/l	77	61	93	8.00	16.00	Tris buffer no P5P IFCC/SFBC 25°C
Amylase Pancreatic	U/l	288	245	331	21.50	43.00	Randox liquid pNPG7 37°C
Amylase Total	U/l	311	264	358	23.50	47.00	Randox liquid stable pNPG7 37°C
AST (GOT)	U/l	139	111	167	14.00	28.00	Tris buffer no P5P IFCC/SFBC 37°C
	U/l	94	75	113	9.50	19.00	Tris buffer no P5P IFCC/SFBC 30°C
	U/l	66	53	79	6.50	13.00	Tris buffer no P5P IFCC/SFBC 25°C
Bilirubin Direct	µmol/l	35.1	27.7	42.5	3.70	7.40	Diazo with Sulphanilic Acid
	mg/dl	2.05	1.62	2.48	0.22	0.43	
Bilirubin Total	µmol/l	90.3	71.3	109	9.50	19.00	Diazo with Sulphanilic Acid
	mg/dl	5.28	4.17	6.39	0.56	1.11	

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Calcium	mmol/l	3.01	2.71	3.31	0.15	0.30	Cresolphthalein complexone
	mg/dl	12.1	10.9	13.3	0.60	1.20	
Chloride	mmol/l	114	105	123	4.50	9.00	ISE direct
Cholesterol	mmol/l	7.26	6.32	8.20	0.47	0.94	Cholesterol Oxidase CDC
	mg/dl	280	244	316	18.00	36.00	
Cholinesterase	U/l	4531	3625	5437	453.00	906.00	Colorimetric Butyrylthiocholine 37°C
CK Total	U/l	505	414	596	45.50	91.00	CK-NAC substrate start (DGKC) 37°C
	U/l	316	259	373	28.50	57.00	CK-NAC substrate start (DGKC) 30°C
	U/l	215	176	254	19.50	39.00	CK-NAC substrate start (DGKC) 25°C
Creatinine	µmol/l	305	250	360	27.50	55.00	Alkaline picrate no deproteinization
	mg/dl	3.45	2.83	4.07	0.31	0.62	
gamma-GT	U/l	180	153	207	13.50	27.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
	U/l	142	121	163	10.50	21.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 30°C
	U/l	111	94	128	8.50	17.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 25°C
GLDH	U/l	32	25	39	3.50	7.00	Triethanolamine buffer 50 mmol 37°C
	U/l	25	19	31	3.00	6.00	Triethanolamine buffer 50 mmol 30°C
	U/l	20	16	24	2.00	4.00	Triethanolamine buffer 50 mmol 25°C
Glucose	mmol/l	14.7	12.5	16.9	1.10	2.20	Glucose oxidase
	mg/dl	265	225	305	20.00	40.00	
Immunoglobulin A	g/l	1.39	1.04	1.74	0.18	0.35	Immunoturbidimetric
	mg/dl	139	104	174	17.50	35.00	
Immunoglobulin G	g/l	6.42	5.26	7.58	0.58	1.16	Immunoturbidimetric
	mg/dl	642	526	758	58.00	116.00	
Immunoglobulin M	g/l	0.86	0.69	1.04	0.09	0.17	Immunoturbidimetric
	mg/dl	86.3	69.0	104	8.65	17.30	

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Iron	µmol/l	37.6	30.8	44.4	3.40	6.80	Colorimetric without ppt.
	µg/dl	210	172	248	19.00	38.00	
Lactate	mmol/l	5.33	4.37	6.29	0.48	0.96	Enzymatic Colorimetric
	mg/dl	48.0	39.4	56.6	4.30	8.60	
LAP	U/l	14	12	16	1.00	2.00	NAGEL 37°C
LD (LDH)	U/l	702	597	807	52.50	105.00	P->L German Methoden 37°C
	U/l	507	431	583	38.00	76.00	P->L German Methoden 30°C
	U/l	356	303	409	26.50	53.00	P->L German Methoden 25°C
Lipase	U/l	98	79	117	9.50	19.00	Randox Colorimetric 37°C
Lithium	mmol/l	1.87	1.65	2.09	0.11	0.22	Spectrophotometric
	mg/dl	1.30	1.15	1.45	0.08	0.15	
Magnesium	mmol/l	1.70	1.50	1.90	0.10	0.20	Xylidyl Blue
	mg/dl	4.13	3.65	4.61	0.24	0.48	
Phosphate Inorganic	mmol/l	2.20	1.87	2.53	0.17	0.33	Phosphomolybdate UV
	mg/dl	6.82	5.80	7.84	0.51	1.02	
Potassium	mmol/l	6.12	5.63	6.61	0.25	0.49	ISE method - direct
Protein Total	g/l	45.8	36.6	55.0	4.60	9.20	Biuret reaction end point
	g/dl	4.58	3.66	5.50	0.46	0.92	
Sodium	mmol/l	165	157	173	4.00	8.00	ISE method - direct
TIBC	µmol/l	39.3	31.0	47.6	4.15	8.30	Direct Colorimetric
	µg/dl	220	173	267	23.50	47.00	
Transferrin	g/l	1.48	1.18	1.78	0.15	0.30	Immunoturbidimetric
	mg/dl	148	118	178	15.00	30.00	
Triglycerides	mmol/l	2.63	2.21	3.05	0.21	0.42	Lipase/GPO-PAP no correction
	mg/dl	233	196	270	18.50	37.00	

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UIBC	µmol/l	1.70	1.39	2.01	0.16	0.31	TIBC - FE
	µg/dl	9.50	7.77	11.2	0.87	1.73	
Urea	mmol/l	18.2	15.5	20.9	1.35	2.70	Urease kinetic
	mg/dl	109	93.2	125	7.90	15.80	
Uric Acid (Urate)	mmol/l	0.53	0.46	0.59	0.03	0.07	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	8.82	7.68	9.96	0.57	1.14	