

CHEMISTRY PREMIUM - LEVEL 2 (CHEM PREMIUM 2)

CAT. NO. HN 5067 **LOT NO.** 957UN
SIZE: 12 x 5 ml **EXP:** 2018-09

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 values section.

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 28 days when frozen once at -20°C (See Limitations).

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

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 1 ml of the serum exactly 30 minutes after reconstitution. After stabilisation Total and Prostatic Acid Phosphatase is stable for 2 hours at +15°C to +25°C, 2 days at +2°C to +8°C, and 28 days 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 is 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 is 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.

PREPARATION FOR USE

Chemistry Premium is supplied lyophilised.

1. Carefully reconstitute each vial of lyophilised serum with exactly 5 ml of distilled water at +15°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 12 x 5 ml

MATERIALS REQUIRED BUT NOT PROVIDED

Volumetric pipette

ASSIGNED VALUES

Each batch of Chemistry Premium is assigned at Randox Laboratories, with reference to an internal master calibrator which is traceable to international Reference Standards.

NOTES

® All trademarks recognized.

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

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Analyte	unit	Target	Range		1SD	2SD	methods
			low	high			
alpha-HBDH	U/l	262	207	317	27.50	55.00	Oxobutyrate < 10 mmol/l 37°C
	U/l	198	156	240	21.00	42.00	Oxobutyrate < 10 mmol/l 30°C
	U/l	148	117	179	15.50	31.00	Oxobutyrate < 10 mmol/l 25°C
Acid Phosphatase (Prostatic)	U/l	9.19	6.16	12.2	1.52	3.03	1-Naphthyl Phosphate substrate Kinetic 37°C
Acid Phosphatase (Total)	U/l	16.2	10.9	21.5	2.65	5.30	1-Naphthyl Phosphate substrate Kinetic 37°C
Albumin	g/l	39.0	33.2	44.8	2.90	5.80	Bromocresol Green
	g/dl	3.90	3.32	4.48	0.29	0.58	
Alkaline Phosphatase	U/l	170	145	195	12.50	25.00	AMP optimised to IFCC 37°C
	U/l	132	113	151	9.50	19.00	AMP optimised to IFCC 30°C
	U/l	109	93	125	8.00	16.00	AMP optimised to IFCC 25°C
	U/l	281	239	323	21.00	42.00	Diethanolamine buffer DEA 37°C
	U/l	219	186	252	16.50	33.00	Diethanolamine buffer DEA 30°C
	U/l	180	153	207	13.50	27.00	Diethanolamine buffer DEA 25°C
ALT (GPT)	U/l	39	31	47	4.00	8.00	Tris buffer without P5P 37°C
	U/l	29	23	35	3.00	6.00	Tris buffer without P5P 30°C
	U/l	22	17	27	2.50	5.00	Tris buffer without P5P 25°C
Amylase Pancreatic	U/l	81	69	93	6.00	12.00	Randox liquid stable pNPG7 37°C
Amylase Total	U/l	100	85	115	7.50	15.00	Randox liquid stable pNPG7 37°C
AST (GOT)	U/l	50	40	60	5.00	10.00	Tris buffer without P5P 37°C
	U/l	34	27	41	3.50	7.00	Tris buffer without P5P 30°C
	U/l	24	19	29	2.50	5.00	Tris buffer without P5P 25°C

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			low	high			
Bilirubin Direct	μmol/l	20.4	16.1	24.7	2.15	4.30	Diazo with Sulphanilic Acid
	mg/dl	1.19	0.942	1.44	0.12	0.25	
Bilirubin Total	μmol/l	31.5	24.9	38.1	3.30	6.60	Diazo with Sulphanilic Acid
	mg/dl	1.84	1.46	2.22	0.19	0.38	
Calcium	mmol/l	2.22	2.00	2.44	0.11	0.22	Cresolphthalein complexone
	mg/dl	8.90	8.02	9.78	0.44	0.88	
Chloride	mmol/l	98.3	90.4	106	3.95	7.90	ISE direct
	mmol/l	96.4	88.7	104	3.85	7.70	ISE indirect
Cholesterol	mmol/l	4.18	3.64	4.72	0.27	0.54	Cholesterol Oxidase
	mg/dl	161	141	181	10.00	20.00	
Cholinesterase	U/l	5268	4214	6322	527.00	1054.00	Colorimetric Butyrylthiocholine 37°C
CK Total	U/l	253	207	299	23.00	46.00	CK-NAC substrate start (DGKC) 37°C
	U/l	158	130	186	14.00	28.00	CK-NAC substrate start (DGKC) 30°C
	U/l	108	88	128	10.00	20.00	CK-NAC substrate start (DGKC) 25°C
Creatinine	μmol/l	117	93.6	140	11.70	23.40	Alkaline picrate no deproteinization
	mg/dl	1.32	1.06	1.58	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	14	11	17	1.50	3.00	Triethanolamine buffer 50 mmol 37°C
	U/l	11	8	14	1.50	3.00	Triethanolamine buffer 50 mmol 30°C
	U/l	9	7	11	1.00	2.00	Triethanolamine buffer 50 mmol 25°C
Glucose	mmol/l	6.28	5.34	7.22	0.47	0.94	Glucose oxidase
	mg/dl	113	96.2	130	8.40	16.80	
Immunoglobulin A	g/l	1.53	1.15	1.91	0.19	0.38	Immunoturbidimetric
	mg/dl	153	115	191	19.00	38.00	

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Immunoglobulin G	g/l	6.13	5.03	7.23	0.55	1.10	Immunoturbidimetric
	mg/dl	613	503	723	55.00	110.00	
Immunoglobulin M	g/l	0.49	0.39	0.58	0.05	0.10	Immunoturbidimetric
	mg/dl	48.5	38.8	58.2	4.85	9.70	
Iron	μmol/l	20.1	16.5	23.7	1.80	3.60	Colorimetric without ppt.
	μg/dl	112	92.2	132	9.90	19.80	
Lactate	mmol/l	1.34	1.10	1.58	0.12	0.24	Colorimetric Lactate Oxidase
	mg/dl	12.1	9.91	14.3	1.10	2.19	
LAP	U/l	16	14	18	1.00	2.00	NAGEL 37°C
LD (LDH)	U/l	440	374	506	33.00	66.00	P->L German methods 37°C
	U/l	318	270	366	24.00	48.00	P->L German methods 30°C
	U/l	223	190	256	16.50	33.00	P->L German methods 25°C
Lipase	U/l	42	34	50	4.00	8.00	Randox Colorimetric 37°C
Lithium	mmol/l	1.09	0.96	1.22	0.07	0.13	Randox Colorimetric
	mg/dl	0.757	0.666	0.848	0.05	0.09	
Magnesium	mmol/l	0.91	0.80	1.02	0.05	0.11	Xylidyl Blue
	mg/dl	2.20	1.94	2.46	0.13	0.26	
Phosphate Inorganic	mmol/l	1.35	1.15	1.55	0.10	0.20	Phosphomolybdate UV
	mg/dl	4.19	3.57	4.81	0.31	0.62	
Potassium	mmol/l	4.28	3.94	4.62	0.17	0.34	ISE direct
	mmol/l	3.95	3.63	4.27	0.16	0.32	ISE indirect
Protein Total	g/l	59.3	47.4	71.2	5.95	11.90	Biuret reaction end point
	g/dl	5.93	4.74	7.12	0.60	1.19	
Sodium	mmol/l	155	147	163	4.00	8.00	ISE direct

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			low	high			
Sodium	mmol/l	142	135	149	3.50	7.00	ISE indirect
TIBC	μmol/l	47.9	37.8	58.0	5.05	10.10	Randox Direct
	μg/dl	268	212	324	28.00	56.00	
Transferrin	g/l	1.85	1.48	2.22	0.19	0.37	Immunoturbidimetric
	mg/dl	185	148	222	18.50	37.00	
Triglycerides	mmol/l	1.12	0.94	1.30	0.09	0.18	Lipase/GPO-PAP no correction
	mg/dl	99.1	83.3	115	7.90	15.80	
UIBC	μmol/l	27.8	22.8	32.8	2.50	5.00	TIBC - FE
	μg/dl	155	127	183	14.00	28.00	
Urea	mmol/l	7.23	6.15	8.31	0.54	1.08	Urease kinetic
	mg/dl	43.5	37.0	50.0	3.25	6.50	
Uric Acid (Urate)	mmol/l	0.35	0.30	0.39	0.02	0.05	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	5.83	5.07	6.59	0.38	0.76	