

CHEMISTRY PREMIUM - LEVEL 2 (CHEM PREMIUM 2)

CAT. NO. HN5067

SIZE: 12 x 5ml

LOT NO. 859UN

EXP: 2017-09

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 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 +15°C to +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 1ml of the serum exactly 30 minutes after reconstitution. After stabilisation Total and Prostatic Acid Phosphatase is stable for 2 hours +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 5ml 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 5ml

MATERIALS REQUIRED BUT NOT PROVIDED

Volumetric pipette

ASSIGNED VALUES

Each batch of Chemistry Premium is assigned at Randox Laboratories Ltd., 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

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Analyte	unit	target	Range		1SD	2SD	methods
			low	high			
alpha-HBDH	U/l	253	200	306	26.50	53.00	Oxobutyrate < 10 mmol/l 37°C
	U/l	191	151	231	20.00	40.00	Oxobutyrate < 10 mmol/l 30°C
	U/l	143	113	173	15.00	30.00	Oxobutyrate < 10 mmol/l 25°C
Acid Phosphatase (Prostatic)	U/l	10.9	7.30	14.5	1.80	3.60	1-Naphthyl Phosphate substrate Kinetic 37°C
Acid Phosphatase (Total)	U/l	17.6	11.8	23.4	2.90	5.80	1-Naphthyl Phosphate substrate Kinetic 37°C
Albumin	g/l	39.3	33.4	45.2	2.95	5.90	Bromocresol Green
	g/dl	3.93	3.34	4.52	0.30	0.59	
Alkaline Phosphatase	U/l	298	253	343	22.50	45.00	Diethanolamine buffer DEA 37°C
	U/l	232	197	267	17.50	35.00	Diethanolamine buffer DEA 30°C
	U/l	190	162	218	14.00	28.00	Diethanolamine buffer DEA 25°C
	U/l	178	151	205	13.50	27.00	AMP optimised to IFCC 37°C
	U/l	139	118	160	10.50	21.00	AMP optimised to IFCC 30°C
	U/l	114	96	132	9.00	18.00	AMP optimised to IFCC 25°C
ALT (GPT)	U/l	36	29	43	3.50	7.00	Tris buffer without P5P 37°C
	U/l	27	21	33	3.00	6.00	Tris buffer without P5P 30°C
	U/l	20	16	24	2.00	4.00	Tris buffer without P5P 25°C
Amylase Pancreatic	U/l	75	64	86	5.50	11.00	Randox liquid stable pNPG7 37°C
Amylase Total	U/l	101	86	116	7.50	15.00	Randox liquid stable pNPG7 37°C
AST (GOT)	U/l	37	30	44	3.50	7.00	Tris buffer without P5P 37°C
	U/l	25	20	30	2.50	5.00	Tris buffer without P5P 30°C
	U/l	18	14	22	2.00	4.00	Tris buffer without P5P 25°C

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Analyte	unit	target	Range		1SD	2SD	methods
			low	high			
Bilirubin Direct	µmol/l	22.1	17.5	26.7	2.30	4.60	Diazo with Sulphanilic Acid
	mg/dl	1.29	1.02	1.56	0.14	0.27	
Bilirubin Total	µmol/l	31.8	25.1	38.5	3.35	6.70	Diazo with Sulphanilic Acid
	mg/dl	1.86	1.47	2.25	0.20	0.39	
Calcium	mmol/l	2.10	1.89	2.31	0.11	0.21	Cresolphthalein complexone
	mg/dl	8.42	7.58	9.26	0.42	0.84	
Chloride	mmol/l	92.4	85.0	99.8	3.70	7.40	ISE indirect
	mmol/l	94.9	87.3	103	3.80	7.60	ISE direct
Cholesterol	mmol/l	4.09	3.56	4.62	0.27	0.53	Cholesterol Oxidase
	mg/dl	158	137	179	10.50	21.00	
Cholinesterase	U/l	4812	3850	5774	481.00	962.00	Colorimetric Butyrylthiocholine 37°C
CK Total	U/l	258	212	304	23.00	46.00	CK-NAC substrate start (DGKC) 37°C
	U/l	162	133	191	14.50	29.00	CK-NAC substrate start (DGKC) 30°C
	U/l	110	90	130	10.00	20.00	CK-NAC substrate start (DGKC) 25°C
Creatinine	µmol/l	115	92.0	138	11.50	23.00	Alkaline picrate no deproteinization
	mg/dl	1.30	1.04	1.56	0.13	0.26	
gamma-GT	U/l	55	47	63	4.00	8.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
	U/l	43	37	49	3.00	6.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 30°C
	U/l	34	29	39	2.50	5.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 25°C
GLDH	U/l	16	13	19	1.50	3.00	Triethanolamine buffer 50 mmol 37°C
	U/l	12	10	14	1.00	2.00	Triethanolamine buffer 50 mmol 30°C
	U/l	10	8	12	1.00	2.00	Triethanolamine buffer 50 mmol 25°C
Glucose	mmol/l	6.49	5.52	7.46	0.49	0.97	Glucose oxidase
	mg/dl	117	99.5	135	8.75	17.50	
Immunoglobulin A	g/l	1.62	1.22	2.02	0.20	0.40	Immunoturbidimetric
	mg/dl	162	122	202	20.00	40.00	

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Immunoglobulin G	g/l	5.40	4.43	6.37	0.49	0.97	Immunoturbidimetric
	mg/dl	540	443	637	48.50	97.00	
Immunoglobulin M	g/l	0.60	0.48	0.72	0.06	0.12	Immunoturbidimetric
	mg/dl	59.7	47.8	71.6	5.95	11.90	
Iron	μmol/l	18.2	14.9	21.5	1.65	3.30	Colorimetric without ppt.
	μg/dl	102	83.3	121	9.35	18.70	
Lactate	mmol/l	1.49	1.22	1.76	0.14	0.27	Colorimetric Lactate Oxidase
	mg/dl	13.4	11.0	15.8	1.20	2.40	
LAP	U/l	14	12	16	1.00	2.00	NAGEL 37°C
LD (LDH)	U/l	422	359	485	31.50	63.00	P->L German methods 37°C
	U/l	305	259	351	23.00	46.00	P->L German methods 30°C
	U/l	214	182	246	16.00	32.00	P->L German methods 25°C
Lipase	U/l	36	29	43	3.50	7.00	Randox Colorimetric 37°C
Lithium	mmol/l	0.91	0.80	1.02	0.06	0.11	Spectrophotometric
	mg/dl	0.634	0.558	0.710	0.04	0.08	
Magnesium	mmol/l	0.90	0.80	1.01	0.05	0.11	Xylidyl Blue
	mg/dl	2.19	1.93	2.45	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	3.68	3.39	3.97	0.15	0.29	ISE indirect
	mmol/l	4.05	3.73	4.37	0.16	0.32	ISE direct
Protein Total	g/l	58.5	46.8	70.2	5.85	11.70	Biuret reaction end point
	g/dl	5.85	4.68	7.02	0.59	1.17	
Sodium	mmol/l	135	128	142	3.50	7.00	ISE indirect

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			low	high			
Sodium	mmol/l	150	143	157	3.50	7.00	ISE direct
TIBC	μmol/l	47.8	37.8	57.8	5.00	10.00	Randox Direct
	μg/dl	267	211	323	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	1.10	0.92	1.28	0.09	0.18	Lipase/GPO-PAP no correction
	mg/dl	97.4	81.8	113	7.80	15.60	
UIBC	μmol/l	29.6	24.3	34.9	2.65	5.30	TIBC - FE
	μg/dl	165	136	194	14.50	29.00	
Urea	mmol/l	6.81	5.79	7.83	0.51	1.02	Urease kinetic
	mg/dl	40.9	34.8	47.0	3.05	6.10	
Uric Acid (Urate)	mmol/l	0.34	0.29	0.38	0.02	0.04	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	5.68	4.94	6.42	0.37	0.74	