

CHEMISTRY PREMIUM - LEVEL 3 (CHEM PREMIUM 3)

CAT. NO. HE5068

SIZE: 12 x 5 ml

LOT NO. 784UE

EXP: 2019-05

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 +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).

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 +15°C to +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.

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 +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 3 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 recognised.

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

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HUMAN ASSAYED SERUM - LEVEL 3 (HUM ASY CONTROL 3)

Cat. No. UE012/002/UL Lot. No. 784UE

Size 5ml	Expiry 2019-05	Range						
Analyte	unit	Target	low	high	1SD	2SD	methods	
alpha-HBDH	U/l	431	340	522	45.50	91.00	Oxobutyrate < 10 mmol/l 37°C	
	U/l	325	257	393	34.00	68.00	Oxobutyrate < 10 mmol/l 30°C	
	U/l	244	192	296	26.00	52.00	Oxobutyrate < 10 mmol/l 25°C	
Acid Phosphatase (Prostatic)	U/l	23.1	15.5	30.7	3.80	7.60	1-Naphthyl Phosphate substrate Kinetic 37°C	
Acid Phosphatase (Total)	U/l	36.0	24.1	47.9	5.95	11.90	1-Naphthyl Phosphate substrate Kinetic 37°C	
Albumin	g/l	27.9	23.7	32.1	2.10	4.20	Bromocresol Green	
	g/dl	2.79	2.37	3.21	0.21	0.42		
Alkaline Phosphatase	U/l	379	322	436	28.50	57.00	AMP optimised to IFCC 37°C	
	U/l	295	251	339	22.00	44.00	AMP optimised to IFCC 30°C	
	U/l	242	206	278	18.00	36.00	AMP optimised to IFCC 25°C	
	U/l	556	473	639	41.50	83.00	Diethanolamine buffer DEA 37°C	
	U/l	433	368	498	32.50	65.00	Diethanolamine buffer DEA 30°C	
	U/l	355	302	408	26.50	53.00	Diethanolamine buffer DEA 25°C	
ALT (GPT)	U/l	151	121	181	15.00	30.00	Tris buffer without P5P 37°C	
	U/l	112	90	134	11.00	22.00	Tris buffer without P5P 30°C	
	U/l	85	68	102	8.50	17.00	Tris buffer without P5P 25°C	
Amylase Pancreatic	U/l	283	241	325	21.00	42.00	Randox liquid stable pNPG7 37°C	
Amylase Total	U/l	311	264	358	23.50	47.00	Randox liquid stable pNPG7 37°C	
AST (GOT)	U/l	185	148	222	18.50	37.00	Tris buffer without P5P 37°C	
	U/l	125	100	150	12.50	25.00	Tris buffer without P5P 30°C	
	U/l	88	70	106	9.00	18.00	Tris buffer without P5P 25°C	

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Size 5ml	Expiry 2019-05	Range					
Analyte	unit	Target	low	high	1SD	2SD	methods
Bilirubin Direct	µmol/l	32.8	25.9	39.7	3.45	6.90	Diazo with Sulphanilic Acid
	mg/dl	1.92	1.52	2.32	0.20	0.40	
Bilirubin Total	µmol/l	96.7	76.4	117	10.15	20.30	Diazo with Sulphanilic Acid
	mg/dl	5.66	4.47	6.85	0.60	1.19	
Calcium	mmol/l	3.07	2.76	3.38	0.16	0.31	Cresolphthalein complexone
	mg/dl	12.3	11.1	13.5	0.60	1.20	
Chloride	mmol/l	116	107	125	4.50	9.00	ISE direct
	mmol/l	114	105	123	4.50	9.00	ISE indirect
Cholesterol	mmol/l	7.28	6.33	8.23	0.48	0.95	Cholesterol Oxidase
	mg/dl	281	244	318	18.50	37.00	
Cholinesterase	U/l	4729	3783	5675	473.00	946.00	Colorimetric Butyrylthiocholine 37°C
CK Total	U/l	534	438	630	48.00	96.00	CK-NAC substrate start (DGKC) 37°C
	U/l	334	274	394	30.00	60.00	CK-NAC substrate start (DGKC) 30°C
	U/l	227	186	268	20.50	41.00	CK-NAC substrate start (DGKC) 25°C
Creatinine	µmol/l	329	263	395	33.00	66.00	Alkaline picrate no deproteinization
	mg/dl	3.72	2.97	4.47	0.38	0.75	
gamma-GT	U/l	187	159	215	14.00	28.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
	U/l	147	125	169	11.00	22.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 30°C
	U/l	115	98	132	8.50	17.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 25°C
GLDH	U/l	30	24	36	3.00	6.00	Triethanolamine buffer 50 mmol 37°C
	U/l	23	18	28	2.50	5.00	Triethanolamine buffer 50 mmol 30°C
	U/l	19	15	23	2.00	4.00	Triethanolamine buffer 50 mmol 25°C
Glucose	mmol/l	16.0	13.6	18.4	1.20	2.40	Glucose oxidase
	mg/dl	288	245	331	21.50	43.00	
Immunoglobulin A	g/l	1.37	1.03	1.71	0.17	0.34	Immunoturbidimetric
	mg/dl	137	103	171	17.00	34.00	

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Size 5ml Expiry 2019-05

Range

Analyte	unit	Target	low	high	1SD	2SD	methods
Immunoglobulin G	g/l	5.23	4.29	6.17	0.47	0.94	Immunoturbidimetric
	mg/dl	523	429	617	47.00	94.00	
Immunoglobulin M	g/l	0.63	0.50	0.75	0.06	0.13	Immunoturbidimetric
	mg/dl	62.6	50.1	75.1	6.25	12.50	
Iron	μmol/l	39.9	32.7	47.1	3.60	7.20	Colorimetric without ppt.
	μg/dl	223	183	263	20.00	40.00	
Lactate	mmol/l	5.24	4.30	6.18	0.47	0.94	Colorimetric Lactate Oxidase
	mg/dl	47.2	38.7	55.7	4.25	8.50	
LAP	U/l	13	11	15	1.00	2.00	NAGEL 37°C
LD (LDH)	U/l	716	609	823	53.50	107.00	P->L German methods 37°C
	U/l	517	440	594	38.50	77.00	P->L German methods 30°C
	U/l	363	309	417	27.00	54.00	P->L German methods 25°C
Lipase	U/l	76	61	91	7.50	15.00	Randox Colorimetric 37°C
Lithium	mmol/l	1.99	1.75	2.23	0.12	0.24	Randox Colorimetric
	mg/dl	1.38	1.22	1.54	0.08	0.16	
Magnesium	mmol/l	1.69	1.49	1.89	0.10	0.20	Xylidyl Blue
	mg/dl	4.11	3.62	4.60	0.25	0.49	
Phosphate Inorganic	mmol/l	2.21	1.88	2.54	0.17	0.33	Phosphomolybdate UV
	mg/dl	6.85	5.83	7.87	0.51	1.02	
Potassium	mmol/l	6.24	5.74	6.74	0.25	0.50	ISE direct
	mmol/l	5.95	5.47	6.43	0.24	0.48	ISE indirect
Protein Total	g/l	43.0	34.4	51.6	4.30	8.60	Biuret reaction end point
	g/dl	4.30	3.44	5.16	0.43	0.86	
Sodium	mmol/l	166	158	174	4.00	8.00	ISE direct

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Analyte	unit	Target	low	high	1SD	2SD	methods
Sodium	mmol/l	160	152	168	4.00	8.00	ISE indirect
TIBC	μmol/l	57.7	45.6	69.8	6.05	12.10	Randox Direct
	μg/dl	323	255	391	34.00	68.00	
Transferrin	g/l	1.61	1.29	1.93	0.16	0.32	Immunoturbidimetric
	mg/dl	161	129	193	16.00	32.00	
Triglycerides	mmol/l	2.91	2.44	3.38	0.24	0.47	Lipase/GPO-PAP no correction
	mg/dl	258	216	300	21.00	42.00	
UIBC	μmol/l	17.8	14.6	21.0	1.60	3.20	TIBC - FE
	μg/dl	99.5	81.6	117	8.95	17.90	
Urea	mmol/l	21.1	17.9	24.3	1.60	3.20	Urease kinetic
	mg/dl	127	108	146	9.50	19.00	
Uric Acid (Urate)	mmol/l	0.55	0.48	0.62	0.04	0.07	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	9.22	8.03	10.4	0.60	1.19	