

HUMAN PRECISION CONTROL - LEVEL 2 (HUM PREC CONTROL 2)

*** TYPICAL VALUES ***

Cat. No. UN1557
Size: 20 x 5 ml

INTENDED USE

This product is intended for *in vitro* diagnostic use as an unassayed control to monitor laboratory precision on clinical chemistry systems.

DEVICE DESCRIPTION

The Precision Human Controls are supplied at 2 levels, level 2 and 3. Typical values are supplied for the most common method 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 30 days when frozen once at -20°C (see Limitations). Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

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

NEFA is stable for 1 day at +2°C to +8°C.

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

The control should not be used as a calibration material.

PREPARATION

The Human Precision Control 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

Human Precision Control Level 2 20 x 5 ml

MATERIALS REQUIRED BUT NOT PROVIDED

Volumetric Pipette

Revised 01 Oct 12 rw

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Analyte	unit	target	methods
alpha-HBDH	U/l	206	Phosphate buffer DGKC 37°C
	U/l	156	Phosphate buffer DGKC 30°C
	U/l	117	Phosphate buffer DGKC 25°C
Acid Phosphatase (Prostatic)	U/l	9.00	1-Naphthyl Phosphate substrate Kinetic 37°C
Acid Phosphatase (Total)	U/l	15.7	1-Naphthyl Phosphate substrate Kinetic 37°C
Albumin	g/l	41.7	Bromocresol Green
	g/dl	4.17	
Alkaline Phosphatase	U/l	210	p-Nitrophenylphosphate AMP 37°C
	U/l	164	p-Nitrophenylphosphate AMP 30°C
	U/l	134	p-Nitrophenylphosphate AMP 25°C
	U/l	301	Diethanolamine buffer DEA 37°C
	U/l	234	Diethanolamine buffer DEA 30°C
	U/l	192	Diethanolamine buffer DEA 25°C
Alpha-1-Acid Glycoprotein	g/l	0.51	Immunoturbidimetric
Alpha-1-Antitrypsin	g/l	1.03	Immunoturbidimetric
Alphafoetoprotein	KIU/l = IU/ml	2.01	Chemiluminescence
	ng/ml	2.43	
ALT (GPT)	U/l	38	Tris buffer no P5P IFCC/SFBC 37°C
	U/l	28	Tris buffer no P5P IFCC/SFBC 30°C
	U/l	21	Tris buffer no P5P IFCC/SFBC 25°C
Amylase Pancreatic	U/l	74	Randox EPS Liquid and BM/Roche EPS Liquid 37°C
Amylase Total	U/l	93	Randox EPS Liquid and BM/Roche EPS Liquid 37°C
	U/l	71	Randox - Ethylidene pNPG7 37°C
Apolipoprotein A-1	g/l	1.08	Immunoturbidimetric
	mg/dl	108	
Apolipoprotein B	g/l	0.71	Immunoturbidimetric
	mg/dl	70.8	
AST (GOT)	U/l	34	Tris buffer no P5P IFCC/SFBC 37°C
	U/l	23	Tris buffer no P5P IFCC/SFBC 30°C
	U/l	16	Tris buffer no P5P IFCC/SFBC 25°C
Bicarbonate	mmol/l	15.3	Enzymatic
Bile Acids	µmol/l	27.3	5th Generation Colorimetric
	µmol/l	28.2	4th Generation Colorimetric
Bilirubin Direct	µmol/l	21.7	Diazo with Sulphanilic Acid
	mg/dl	1.27	
Bilirubin Total	µmol/l	33.2	Diazo with Sulphanilic Acid
	mg/dl	1.94	
C-Reactive Protein	mg/l	1.43	Immunoturbidimetric
Caeruloplasmin	g/l	0.235	Nephelometric
Calcium	mmol/l	2.20	Arsenazo III
	mg/dl	8.82	

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Analyte	unit	target	methods
Carbamazepine	μmol/l	33.8	Immunoturbidimetric
	μg/ml	7.99	
Carcinoembryonic Antigen (CEA)	ng/ml = μg/l	1.15	Nephelometric
Chloride	mmol/l	98.7	ISE direct
Cholesterol	mmol/l	4.18	Cholesterol Oxidase
	mg/dl	161	
Cholinesterase	U/l	5277	Colorimetric 37°C
CK Total	U/l	211	Phosphate buffer DGKC 37°C
	U/l	132	Phosphate buffer DGKC 30°C
	U/l	90	Phosphate buffer DGKC 25°C
Complement C3	g/l	0.88	Immunoturbidimetric
Complement C4	g/l	0.17	Immunoturbidimetric
Copper	μmol/l	17.5	Colorimetric
	μg/dl	111	
Cortisol	nmol/l	478	Chemiluminescence
	μg/dl	17.2	
Creatinine	μmol/l	127	Alkaline picrate no deproteinization
	mg/dl	1.44	
	μmol/l	128	Randox Enzymatic UV method
	mg/dl	1.45	
D-3-Hydroxybutyrate	mmol/l	0.30	Enzymatic
Digoxin	nmol/l	2.38	Immunoturbidimetric
	ng/ml	1.86	
Ferritin	ng/ml = μg/l	43.2	Immunoturbidimetric
Folate	nmol/l	42.4	Chemiluminescence
	ng/ml	18.7	
Free T3	pmol/l	10.6	Chemiluminescence
	ng/dl	0.69	
	pg/ml	6.90	
Free Thyroxine (FT4)	pmol/l	24.8	Chemiluminescence
	pg/ml	19.3	
Gentamicin	μmol/l	7.17	Immunoturbidimetric
	μg/ml	3.32	
gamma-GT	U/l	49	Gamma glutamyl.-3-carboxy-4-nitroanilide 37°C
	U/l	39	Gamma glutamyl.-3-carboxy-4-nitroanilide 30°C
	U/l	30	Gamma glutamyl.-3-carboxy-4-nitroanilide 25°C
GLDH	U/l	18	DGKC 37°C
	U/l	14	DGKC 30°C
	U/l	11	DGKC 25°C
Glucose	mmol/l	6.15	Glucose oxidase
	mg/dl	111	
Haptoglobin	g/l	0.83	Nephelometric

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Analyte	unit	target	methods
HDL - Cholesterol	mmol/l	1.14	Direct Clearance Method
	mg/dl	44.0	
Immunoglobulin A	g/l	1.87	Immunoturbidimetric
Immunoglobulin E	KIU/l = IU/ml	103	Immunoturbidimetric
Immunoglobulin G	g/l	8.32	Immunoturbidimetric
Immunoglobulin M	g/l	0.71	Immunoturbidimetric
Iron	µmol/l	19.3	Colorimetric without ppt.
	µg/dl	108	
Lactate	mmol/l	1.45	Enzymatic Colorimetric
	mg/dl	13.1	
LAP	U/l	17	NAGEL 37°C
LD (LDH)	U/l	402	Phosphate buffer DGKC 37°C
	U/l	290	Phosphate buffer DGKC 30°C
	U/l	204	Phosphate buffer DGKC 25°C
Lipase	U/l	41	Randox Colorimetric 37°C
	U/l	161	Turbidimetric 37°C
Lithium	mmol/l	1.00	Colorimetric
	mg/dl	0.69	
Magnesium	mmol/l	0.92	Xylidyl Blue
	mg/dl	2.24	
Myoglobin	ng/ml	46.6	Immunoturbidimetric
NEFA	mmol/l	1.45	Colorimetric
Osmolality	mmol/kg	313	Freezing point depression
Paracetamol	mmol/l	0.05	Polarisation Fluoroimmunoassay
	mg/l	7.90	
Phenobarbital	µmol/l	122	Immunoturbidimetric
	µg/ml	28.3	
Phenytoin	µmol/l	59.4	Immunoturbidimetric
	µg/ml	15.0	
Phosphate Inorganic	mmol/l	1.46	Phosphomolybdate UV
	mg/dl	4.53	
Potassium	mmol/l	3.85	ISE direct
Prealbumin	g/l	0.21	Immunoturbidimetric
Prolactin	µU/ml	176	Chemiluminescence
Protein Total	g/l	60.3	Biuret reaction end point
	g/dl	6.03	
PSA Total	ng/ml = µg/l	10.4	Chemiluminescence
Salicylate	mmol/l	0.45	Colorimetric Trinder
	mg/dl	6.21	
Sodium	mmol/l	139	ISE direct
Theophylline	µmol/l	26.9	Immunoturbidimetric
	µg/ml	4.85	
Thyroid Stimulating Hormone	µU/ml = mIU/l	1.42	Chemiluminescence

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Thyroxine (T4)	nmol/l	95.5	Chemiluminescence
	µg/dl	7.45	
TIBC	µmol/l	43.1	Direct Colorimetric
	µg/dl	241	
	µmol/l	46.8	FE+UIBC(saturation with iron)
	µg/dl	262	
Tobramycin	µmol/l	5.77	Polarisation Fluoroimmunoassay
	µg/ml	2.70	
Total Beta hCG	mU/ml	25.8	Chemiluminescence
Transferrin	g/l	1.97	Immunoturbidimetric
Triglycerides	mmol/l	1.06	Enzymatic Colorimetric
	mg/dl	93.8	
Triiodothyronine (T3)	nmol/l	2.34	Chemiluminescence
	ng/ml	1.52	
Troponin I	ng/ml = µg/l	0.25	Chemiluminescence
UIBC	µmol/l	27.5	TIBC - FE
	µg/dl	154	
Urea	mmol/l	7.12	Enzymatic
	mg/dl	42.8	
	mmol/l	6.34	Urease Berthelot
	mg/dl	38.1	
	mmol/l	7.25	Urease hypochlorite
	mg/dl	43.6	
	mmol/l	7.12	BUN
	mg/dl	20.0	
Uric Acid (Urate)	mmol/l	0.337	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	5.66	
Valproic Acid	µmol/l	500	Immunoturbidimetric
	µg/ml	72.2	
Vancomycin	µmol/l	10.3	Polarisation Fluoroimmunoassay
	µg/ml	15.3	
Vitamin B12	pmol/l	441	Chemiluminescence
	pg/ml	598	
Zinc	µmol/l	29.6	Colorimetric
	µg/dl	193	