

DRUG CONTROL - LEVEL I (TDM CONTROL I)

Cat. No. HD1667 **Lot No.** 662DC
Size: 20 x 5ml **Expiry:** 2017-12

INTENDED USE

This product is intended for *in vitro* diagnostic use in the quality control of drug residue analysis on clinical chemistry systems. The Drug Controls are for the control of accuracy and precision.

DEVICE DESCRIPTION

The Drug Controls are supplied at 3 levels, level 1, 2 and 3. Target values and ranges are supplied for the analytes listed in the values section at 3 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, which has been added, 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 4 weeks at +2°C to +8°C, if kept capped in original container and free from contamination. 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.

PREPARATION FOR USE

The Drug Controls are 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

Drug Control - Level I 20 x 5ml

MATERIALS REQUIRED BUT NOT PROVIDED

Volumetric pipette

ASSIGNED VALUES

Each batch of serum is distributed to approximately 250 laboratories and values are assigned by a consensus of results obtained by these laboratories. A control range for individual parameters and for each parameter method is provided for each batch of serum. The control range is equivalent to the assigned mean ± 2 S.D.

If a method is unavailable, contact Randox Laboratories - Technical Services, Northern Ireland, tel: +44 (0) 28 9445 1070 or email Technical.Services@randox.com

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DRUG CONTROL - LEVEL 1 (TDM CONTROL 1)

Cat. No. HD1667 Lot No. 662DC Size: 20 x 5ml Expiry: 2017-12

Range					
Analyte	unit	target	low	high	methods
Amikacin	µmol/l	6.50	4.77	8.23	Enzyme Immunoassay
	µg/ml	3.81	2.79	4.83	
	µmol/l	6.38	5.10	7.66	Polarisation Fluoroimmunoassay
	µg/ml	3.74	2.99	4.49	
	µmol/l	5.89	4.71	7.07	KIMS
	µg/ml	3.45	2.76	4.14	
	µmol/l	6.43	5.14	7.72	Turbidimetric
	µg/ml	3.77	3.01	4.53	
Caffeine	µmol/l	14.5	10.9	18.1	Enzyme Immunoassay
	µg/ml	2.81	2.12	3.50	
Carbamazepine	µmol/l	13.8	11.0	16.6	Enzyme Immunoassay
	µg/ml	3.26	2.60	3.92	
	µmol/l	13.0	10.0	16.0	HPLC (Reverse Phase)
	µg/ml	3.07	2.36	3.78	
	µmol/l	13.1	10.5	15.7	Polarisation Fluoroimmunoassay
	µg/ml	3.10	2.48	3.72	
	µmol/l	12.7	10.2	15.2	Ortho Vitros Microslide Systems
	µg/ml	3.00	2.41	3.59	
	µmol/l	12.0	9.60	14.4	Chemiluminescence
	µg/ml	2.84	2.27	3.41	
	µmol/l	12.3	9.84	14.8	Turbidimetric
	µg/ml	2.91	2.33	3.49	
	µmol/l	12.9	10.3	15.5	Roche Integra
	µg/ml	3.05	2.43	3.67	
	µmol/l	12.2	9.76	14.6	KIMS
	µg/ml	2.88	2.31	3.45	
Cyclosporin	nmol/l	73.4	58.7	88.1	Enzyme Immunoassay
	ng/ml	88.3	70.6	106	
	nmol/l	100	80.0	120	Chemiluminescence
	ng/ml	120	96.2	144	
Digoxin	nmol/l	0.593	0.416	0.770	Vitros
	ng/ml	0.463	0.325	0.600	
	nmol/l	0.636	0.501	0.771	Chemiluminescence
	ng/ml	0.497	0.391	0.600	
	nmol/l	0.645	0.485	0.805	Enzyme Immunoassay
	ng/ml	0.504	0.379	0.630	
	nmol/l	0.649	0.501	0.797	KIMS
	ng/ml	0.507	0.391	0.620	
	nmol/l	0.622	0.450	0.794	Turbidimetric
	ng/ml	0.486	0.351	0.620	
Ethosuximide	µmol/l	271	217	325	Enzyme Immunoassay
	µg/ml	38.4	30.8	46.0	

DRUG CONTROL - LEVEL 1 (TDM CONTROL 1)

Cat. No. HD1667 Lot No. 662DC Size: 20 x 5ml Expiry: 2017-12

Range					
Analyte	unit	target	low	high	methods
Ethosuximide	µmol/l	267	214	320	HPLC (Reverse Phase)
	µg/ml	37.9	30.3	45.5	
Gentamicin	µmol/l	4.48	3.58	5.38	Enzyme Immunoassay
	µg/ml	2.14	1.71	2.57	
	µmol/l	4.55	3.64	5.46	Polarisation Fluoroimmunoassay
	µg/ml	2.17	1.74	2.60	
	µmol/l	4.47	3.58	5.36	Chemiluminescence
	µg/ml	2.14	1.71	2.57	
	µmol/l	4.61	3.69	5.53	Turbidimetric
	µg/ml	2.20	1.76	2.64	
Lithium	µmol/l	3.57	2.69	4.45	KIMS
	µg/ml	1.71	1.29	2.13	
	mmol/l	0.492	0.397	0.587	Ion selective electrode
	mg/dl	0.342	0.276	0.410	
Lithium (Vitros)	mmol/l	0.518	0.454	0.582	Spectrophotometric
	mg/dl	0.360	0.315	0.410	
	mmol/l	0.850	0.680	1.02	Vitros
	mg/dl	0.590	0.472	0.708	
Methotrexate	µmol/l	0.380	0.304	0.456	Enzyme Immunoassay
	µg/ml	0.173	0.138	0.208	
	µmol/l	0.370	0.296	0.444	Polarisation Fluoroimmunoassay
	µg/ml	0.168	0.135	0.201	
Paracetamol	mmol/l	0.190	0.152	0.228	Vitros
	mg/l	28.7	23.0	34.4	
	mmol/l	0.142	0.114	0.170	Colorimetric
	mg/l	21.5	17.2	25.8	
	mmol/l	0.196	0.140	0.252	Polarisation Fluoroimmunoassay
	mg/l	29.7	21.2	38.2	
	mmol/l	0.170	0.136	0.204	Enzymatic
	mg/l	25.7	20.6	30.8	
	mmol/l	0.200	0.160	0.240	Turbidimetric
	mg/l	30.3	24.2	36.4	
Phenobarbital	µmol/l	34.6	27.7	41.5	Enzyme Immunoassay
	µg/ml	8.03	6.43	9.63	
	µmol/l	36.3	29.0	43.6	Polarisation Fluoroimmunoassay
	µg/ml	8.42	6.73	10.1	
	µmol/l	31.9	25.5	38.3	HPLC (Reverse Phase)
	µg/ml	7.40	5.92	8.88	
	µmol/l	36.8	29.4	44.2	Turbidimetric
	µg/ml	8.54	6.82	10.3	
	µmol/l	37.0	29.6	44.4	Chemiluminescence
	µg/ml	8.58	6.87	10.3	
Phenytoin	µmol/l	36.6	29.3	43.9	KIMS
	µg/ml	8.49	6.80	10.2	
Phenytoin	µmol/l	18.2	14.6	21.8	Vitros
	µg/ml	4.60	3.69	5.51	

DRUG CONTROL - LEVEL 1 (TDM CONTROL 1)

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Analyte	unit	target	low	high	methods
Phenytoin	µmol/l	19.9	15.7	24.1	Enzyme Immunoassay
	µg/ml	5.02	3.96	6.08	
	µmol/l	19.9	14.7	25.1	HPLC (Reverse Phase)
	µg/ml	5.02	3.71	6.33	
	µmol/l	19.2	15.4	23.0	Polarisation Fluoroimmunoassay
	µg/ml	4.85	3.89	5.81	
	µmol/l	20.2	16.2	24.2	Turbidimetric
	µg/ml	5.10	4.09	6.11	
Primidone	µmol/l	20.1	16.1	24.1	Chemiluminescence
	µg/ml	5.08	4.07	6.09	
	µmol/l	18.6	14.9	22.3	KIMS
	µg/ml	4.70	3.76	5.64	
Phenylethynolone	µmol/l	13.9	11.1	16.7	Polarisation Fluoroimmunoassay
	µg/ml	3.03	2.42	3.64	
Salicylic Acid	mmol/l	0.310	0.248	0.372	Vitros
	mg/dl	4.28	3.43	5.13	
	mmol/l	0.270	0.216	0.324	Colorimetric Trinder
	mg/dl	3.73	2.98	4.48	
	mmol/l	0.190	0.152	0.228	Polarisation Fluoroimmunoassay
	mg/dl	2.62	2.10	3.14	
Theophylline	mmol/l	0.240	0.192	0.288	Enzymatic
	mg/dl	3.31	2.65	3.97	
	µmol/l	24.5	19.6	29.4	Vitros
	µg/ml	4.41	3.53	5.29	
	µmol/l	30.5	24.4	36.6	Chemiluminescence
	µg/ml	5.50	4.40	6.60	
Tobramycin	µmol/l	28.7	21.8	35.6	Enzyme Immunoassay
	µg/ml	5.17	3.93	6.41	
	µmol/l	30.3	24.2	36.4	Polarisation Fluoroimmunoassay
	µg/ml	5.46	4.36	6.56	
	µmol/l	28.8	23.0	34.6	Turbidimetric
	µg/ml	5.19	4.14	6.24	
Valproic Acid	µmol/l	28.9	23.1	34.7	KIMS
	µg/ml	5.21	4.16	6.26	
	µmol/l	4.27	3.42	5.12	Enzyme Immunoassay
	µg/ml	2.00	1.60	2.40	
Valproic Acid	µmol/l	3.66	2.93	4.39	Polarisation Fluoroimmunoassay
	µg/ml	1.71	1.37	2.05	
	µmol/l	4.32	3.07	5.57	Turbidimetric
	µg/ml	2.02	1.44	2.60	
Valproic Acid	µmol/l	234	187	281	Enzyme Immunoassay
	µg/ml	33.8	27.0	40.6	
	µmol/l	218	174	262	Polarisation Fluoroimmunoassay
	µg/ml	31.5	25.1	37.9	
Valproic Acid	µmol/l	227	182	272	Chemiluminescence
	µg/ml	32.8	26.3	39.3	

DRUG CONTROL - LEVEL 1 (TDM CONTROL 1)

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Range					
Analyte	unit	target	low	high	methods
Valproic Acid	µmol/l	221	177	265	Turbidimetric
	µg/ml	31.9	25.5	38.3	
Vancomycin	µmol/l	3.10	2.48	3.72	Enzyme Immunoassay
	µg/ml	4.61	3.68	5.54	
	µmol/l	4.10	2.95	5.25	Polarisation Fluoroimmunoassay
	µg/ml	6.09	4.38	7.80	
	µmol/l	2.80	2.24	3.36	Chemiluminescence
	µg/ml	4.16	3.33	4.99	
	µmol/l	2.91	2.33	3.49	Turbidimetric
	µg/ml	4.32	3.46	5.18	