DRUG CONTROL - LEVEL 1 (TDM CONTROL 1)

Cat No. HD1667 **Lot No.** 715DC
Size: 20 x 5 ml **Expiry:** 2019-01

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 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 the 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 1 20 x 5 ml

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: (028) 9445 1070 or email Technical.Services@randox.com.

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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Amikacin	µmol/l	6.63	5.30	7.96	Enzyme Immunoassay
	µg/ml	3.88	3.10	4.66	
	µmol/l	6.71	5.37	8.05	Polarisation Fluoroimmunoassay
	µg/ml	3.93	3.14	4.72	
	µmol/l	6.71	5.37	8.05	KIMS
	µg/ml	3.93	3.14	4.72	
	µmol/l	6.50	5.20	7.80	Turbidimetric
	µg/ml	3.81	3.05	4.57	
Caffeine	µmol/l	14.9	11.2	18.6	Enzyme Immunoassay
	µg/ml	2.89	2.17	3.61	
Carbamazepine	µmol/l	15.2	12.2	18.2	Enzyme Immunoassay
	µg/ml	3.59	2.88	4.30	
	µmol/l	14.1	11.3	16.9	Polarisation Fluoroimmunoassay
	µg/ml	3.33	2.67	3.99	
	µmol/l	9.73	7.78	11.7	Ortho Vitros Microslide Systems
	µg/ml	2.30	1.84	2.76	
	µmol/l	12.4	9.92	14.9	Chemiluminescence
	µg/ml	2.93	2.35	3.51	
	µmol/l	12.6	10.1	15.1	Turbidimetric
	µg/ml	2.98	2.39	3.57	
	µmol/l	12.8	10.2	15.4	KIMS
	µg/ml	3.03	2.41	3.65	
Cyclosporin	nmol/l	90.1	72.1	108	Enzyme Immunoassay
	ng/ml	108	86.7	129	
	nmol/l	98.7	79.0	118	Chemiluminescence
	ng/ml	119	95.0	143	
Digoxin	nmol/l	0.668	0.534	0.802	Vitros
	ng/ml	0.522	0.417	0.627	
	nmol/l	0.605	0.484	0.726	Chemiluminescence
	ng/ml	0.473	0.378	0.568	
	nmol/l	0.677	0.542	0.812	Enzyme Immunoassay
	ng/ml	0.529	0.423	0.635	
	nmol/l	0.699	0.559	0.839	KIMS
	ng/ml	0.546	0.437	0.655	
	nmol/l	0.597	0.478	0.716	Turbidimetric
	ng/ml	0.466	0.373	0.559	
Ethosuximide	µmol/l	303	242	364	HPLC (Reverse Phase)
	µg/ml	43.0	34.3	51.7	
Gentamicin	µmol/l	4.99	3.99	5.99	Enzyme Immunoassay
	µg/ml	2.39	1.91	2.87	
	µmol/l	4.92	3.94	5.90	Polarisation Fluoroimmunoassay
	µg/ml	2.35	1.88	2.82	

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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Gentamicin	µmol/l	4.77	3.82	5.72	Chemiluminescence
	µg/ml	2.28	1.83	2.73	
	µmol/l	5.15	4.12	6.18	Turbidimetric
	µg/ml	2.46	1.97	2.95	
	µmol/l	3.53	2.82	4.24	KIMS
	µg/ml	1.69	1.35	2.03	
Lithium	mmol/l	0.507	0.446	0.568	Ion selective electrode
	mg/dl	0.352	0.310	0.394	
	mmol/l	0.547	0.481	0.613	Spectrophotometric
	mg/dl	0.380	0.334	0.426	
Lithium (Vitros)	mmol/l	0.818	0.654	0.982	Vitros
	mg/dl	0.568	0.454	0.682	
Methotrexate	µmol/l	0.406	0.325	0.487	Enzyme Immunoassay
	µg/ml	0.184	0.148	0.220	
	µmol/l	0.403	0.322	0.484	Polarisation Fluoroimmunoassay
	µg/ml	0.183	0.146	0.220	
Paracetamol	mmol/l	0.187	0.150	0.224	Vitros
	mg/l	28.3	22.7	33.9	
	mmol/l	0.152	0.122	0.182	Colorimetric
	mg/l	23.0	18.5	27.5	
	mmol/l	0.170	0.136	0.204	Enzymatic
	mg/l	25.7	20.6	30.8	
	mmol/l	0.195	0.156	0.234	Turbidimetric
	mg/l	29.5	23.6	35.4	
	mmol/l	0.211	0.169	0.253	Siemens Dimension Enzymatic
	mg/l	31.9	25.6	38.2	
Phenobarbital	µmol/l	35.2	28.2	42.2	Enzyme Immunoassay
	µg/ml	8.17	6.54	9.80	
	µmol/l	32.8	26.2	39.4	Polarisation Fluoroimmunoassay
	µg/ml	7.61	6.08	9.14	
	µmol/l	36.4	29.1	43.7	Turbidimetric
	µg/ml	8.44	6.75	10.1	
	µmol/l	34.9	27.9	41.9	Chemiluminescence
	µg/ml	8.10	6.47	9.73	
	µmol/l	34.6	27.7	41.5	KIMS
	µg/ml	8.03	6.43	9.63	
	µmol/l	39.0	31.2	46.8	HPLC (Reverse Phase)
	µg/ml	9.05	7.24	10.9	
Phenytoin	µmol/l	17.7	14.2	21.2	Vitros
	µg/ml	4.47	3.59	5.35	
	µmol/l	19.5	15.6	23.4	Enzyme Immunoassay
	µg/ml	4.92	3.94	5.90	
	µmol/l	18.6	14.9	22.3	Polarisation Fluoroimmunoassay
	µg/ml	4.70	3.76	5.64	
	µmol/l	19.5	15.6	23.4	Turbidimetric
	µg/ml	4.92	3.94	5.90	

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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Phenytoin	µmol/l	20.0	16.0	24.0	Chemiluminescence
	µg/ml	5.05	4.04	6.06	
	µmol/l	19.0	15.2	22.8	KIMS
	µg/ml	4.80	3.84	5.76	
	µmol/l	19.6	15.7	23.5	HPLC (Reverse Phase)
	µg/ml	4.95	3.96	5.93	
Primidone	µmol/l	14.7	10.3	19.1	Polarisation Fluoroimmunoassay
	µg/ml	3.21	2.25	4.17	
Salicylic Acid	mmol/l	0.309	0.247	0.371	Vitros
	mg/dl	4.27	3.41	5.13	
	mmol/l	0.266	0.213	0.319	Colorimetric Trinder
	mg/dl	3.67	2.94	4.40	
	mmol/l	0.253	0.202	0.304	Enzymatic
	mg/dl	3.49	2.79	4.19	
Theophylline	µmol/l	25.3	20.2	30.4	Vitros
	µg/ml	4.56	3.64	5.48	
	µmol/l	28.9	23.1	34.7	Chemiluminescence
	µg/ml	5.21	4.16	6.26	
	µmol/l	29.5	23.6	35.4	Enzyme Immunoassay
	µg/ml	5.32	4.25	6.39	
	µmol/l	30.4	24.3	36.5	Polarisation Fluoroimmunoassay
	µg/ml	5.48	4.38	6.58	
	µmol/l	28.8	23.0	34.6	Turbidimetric
	µg/ml	5.19	4.14	6.24	
	µmol/l	28.7	23.0	34.4	KIMS
	µg/ml	5.17	4.14	6.20	
Tobramycin	µmol/l	4.18	3.34	5.02	Enzyme Immunoassay
	µg/ml	1.96	1.56	2.36	
	µmol/l	4.03	3.22	4.84	Polarisation Fluoroimmunoassay
	µg/ml	1.89	1.51	2.27	
	µmol/l	4.13	3.30	4.96	Turbidimetric
	µg/ml	1.93	1.54	2.32	
Valproic Acid	µmol/l	229	183	275	Enzyme Immunoassay
	µg/ml	33.0	26.4	39.6	
	µmol/l	216	173	259	Polarisation Fluoroimmunoassay
	µg/ml	31.2	25.0	37.4	
	µmol/l	227	182	272	Chemiluminescence
	µg/ml	32.8	26.3	39.3	
	µmol/l	225	180	270	Turbidimetric
	µg/ml	32.5	26.0	39.0	
Vancomycin	µmol/l	3.60	2.88	4.32	Enzyme Immunoassay
	µg/ml	5.35	4.28	6.42	
	µmol/l	4.08	3.26	4.90	Polarisation Fluoroimmunoassay
	µg/ml	6.06	4.84	7.28	
	µmol/l	3.16	2.53	3.79	Chemiluminescence
	µg/ml	4.69	3.76	5.62	

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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Vancomycin	µmol/l	3.15	2.52	3.78	Turbidimetric
	µg/ml	4.68	3.74	5.62	