DRUG CONTROL - LEVEL 3 (TDM CONTROL 3)

Cat. No. HD1669 **Lot No.** 667DC
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.

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 3 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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			Range		
Analyte	**unit**	**target**	**low**	**high**	**methods**
Amikacin	µmol/l	45.5	36.4	54.6	Enzyme Immunoassay
	µg/ml	26.6	21.3	31.9	
	µmol/l	46.0	36.8	55.2	Polarisation Fluoroimmunoassay
	µg/ml	26.9	21.6	32.2	
	µmol/l	47.2	37.8	56.6	KIMS
	µg/ml	27.6	22.1	33.1	
	µmol/l	48.6	38.9	58.3	Turbidimetric
	µg/ml	28.5	22.8	34.2	
Caffeine	µmol/l	71.4	53.6	89.3	Enzyme Immunoassay
	µg/ml	13.9	10.4	17.4	
Carbamazepine	µmol/l	68.9	55.1	82.7	Enzyme Immunoassay
	µg/ml	16.3	13.0	19.6	
	µmol/l	67.6	54.1	81.1	HPLC (Reverse Phase)
	µg/ml	16.0	12.8	19.2	
	µmol/l	70.4	56.3	84.5	Polarisation Fluoroimmunoassay
	µg/ml	16.6	13.3	19.9	
	µmol/l	50.0	40.0	60.0	Ortho Vitros Microslide Systems
	µg/ml	11.8	9.46	14.1	
	µmol/l	59.1	47.3	70.9	Chemiluminescence
	µg/ml	14.0	11.2	16.8	
	µmol/l	65.2	52.2	78.2	Turbidimetric
	µg/ml	15.4	12.3	18.5	
	µmol/l	66.0	52.8	79.2	Roche Integra
	µg/ml	15.6	12.5	18.7	
	µmol/l	64.9	51.9	77.9	KIMS
	µg/ml	15.3	12.3	18.3	
Cyclosporin	nmol/l	629	503	755	Chemiluminescence
	ng/ml	756	605	907	
Digoxin	nmol/l	3.74	2.99	4.49	Vitros
	ng/ml	2.92	2.34	3.50	
	nmol/l	4.42	3.40	5.44	Chemiluminescence
	ng/ml	3.45	2.66	4.24	
	nmol/l	4.09	3.27	4.91	Enzyme Immunoassay
	ng/ml	3.19	2.55	3.83	
	nmol/l	4.45	3.56	5.34	Polarisation Fluoroimmunoassay
	ng/ml	3.48	2.78	4.18	
	nmol/l	3.91	3.13	4.69	Beckman CX/LX/Immage
	ng/ml	3.05	2.44	3.66	
	nmol/l	3.77	3.02	4.52	KIMS
	ng/ml	2.94	2.36	3.52	
	nmol/l	3.99	3.19	4.79	Turbidimetric
	ng/ml	3.12	2.49	3.75	

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DRUG CONTROL - LEVEL 3 (TDM CONTROL 3)

Cat. No. HD1669 Lot No. 667DC Size: 20 x 5ml Expiry: 2017-12

			Range		
Analyte	**unit**	**target**	**low**	**high**	**methods**
Ethosuximide	µmol/l	742	594	890	HPLC (Reverse Phase)
	µg/ml	105	84.2	126	
Gentamicin	µmol/l	16.5	13.2	19.8	Enzyme Immunoassay
	µg/ml	7.89	6.31	9.47	
	µmol/l	15.7	12.6	18.8	Polarisation Fluoroimmunoassay
	µg/ml	7.50	6.02	8.98	
	µmol/l	17.9	14.3	21.5	Chemiluminescence
	µg/ml	8.56	6.84	10.3	
	µmol/l	16.5	13.2	19.8	Turbidimetric
	µg/ml	7.89	6.31	9.47	
	µmol/l	12.4	9.92	14.9	KIMS
	µg/ml	5.93	4.74	7.12	
Lithium	mmol/l	1.79	1.58	2.00	Ion selective electrode
	mg/dl	1.24	1.10	1.38	
	mmol/l	1.80	1.58	2.02	Spectrophotometric
	mg/dl	1.25	1.10	1.40	
Lithium (Vitros)	mmol/l	2.36	1.89	2.83	Vitros
	mg/dl	1.64	1.31	1.97	
Methotrexate	µmol/l	8.42	6.18	10.7	Enzyme Immunoassay
	µg/ml	3.83	2.81	4.85	
	µmol/l	8.92	7.14	10.7	Polarisation Fluoroimmunoassay
	µg/ml	4.05	3.24	4.86	
Paracetamol	mmol/l	1.46	1.17	1.75	Vitros
	mg/l	221	177	265	
	mmol/l	1.31	1.05	1.57	Colorimetric
	mg/l	198	159	237	
	mmol/l	1.34	1.07	1.61	Polarisation Fluoroimmunoassay
	mg/l	203	162	244	
	mmol/l	1.34	1.07	1.61	Enzymatic
	mg/l	203	162	244	
	mmol/l	1.49	1.19	1.79	Turbidimetric
	mg/l	225	180	270	
Phenobarbital	µmol/l	219	175	263	Enzyme Immunoassay
	µg/ml	50.8	40.6	61.0	
	µmol/l	207	166	248	Polarisation Fluoroimmunoassay
	µg/ml	48.0	38.5	57.5	
	µmol/l	203	162	244	HPLC (Reverse Phase)
	µg/ml	47.1	37.6	56.6	
	µmol/l	217	174	260	Turbidimetric
	µg/ml	50.3	40.4	60.2	
	µmol/l	223	178	268	Chemiluminescence
	µg/ml	51.7	41.3	62.1	
	µmol/l	216	173	259	KIMS
	µg/ml	50.1	40.1	60.1	
Phenytoin	µmol/l	87.2	69.8	105	Vitros
	µg/ml	22.0	17.6	26.4	

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Analyte	**unit**	**target**	**low**	**high**	**methods**
Phenytoin	µmol/l	97.1	77.7	117	Enzyme Immunoassay
	µg/ml	24.5	19.6	29.4	
	µmol/l	94.2	75.4	113	HPLC (Reverse Phase)
	µg/ml	23.8	19.0	28.6	
	µmol/l	92.2	73.8	111	Polarisation Fluoroimmunoassay
	µg/ml	23.3	18.6	28.0	
	µmol/l	95.9	76.7	115	Turbidimetric
	µg/ml	24.2	19.4	29.0	
	µmol/l	96.2	77.0	115	Chemiluminescence
	µg/ml	24.3	19.4	29.2	
	µmol/l	91.9	73.5	110	KIMS
	µg/ml	23.2	18.6	27.8	
Primidone	µmol/l	57.2	45.8	68.6	Polarisation Fluoroimmunoassay
	µg/ml	12.5	10.0	15.0	
Salicylic Acid	mmol/l	2.92	2.34	3.50	Vitros
	mg/dl	40.3	32.3	48.3	
	mmol/l	2.71	2.17	3.25	Colorimetric Trinder
	mg/dl	37.4	30.0	44.8	
	mmol/l	2.82	2.26	3.38	Enzymatic
	mg/dl	38.9	31.2	46.6	
Theophylline	µmol/l	194	155	233	Vitros
	µg/ml	35.0	27.9	42.1	
	µmol/l	170	136	204	Chemiluminescence
	µg/ml	30.6	24.5	36.7	
	µmol/l	168	134	202	Enzyme Immunoassay
	µg/ml	30.3	24.1	36.5	
	µmol/l	170	136	204	Polarisation Fluoroimmunoassay
	µg/ml	30.6	24.5	36.7	
	µmol/l	166	133	199	Turbidimetric
	µg/ml	29.9	24.0	35.8	
	µmol/l	167	134	200	KIMS
	µg/ml	30.1	24.1	36.1	
Tobramycin	µmol/l	17.5	14.0	21.0	Enzyme Immunoassay
	µg/ml	8.19	6.55	9.83	
	µmol/l	15.5	12.4	18.6	Polarisation Fluoroimmunoassay
	µg/ml	7.25	5.80	8.70	
	µmol/l	17.2	13.8	20.6	Turbidimetric
	µg/ml	8.05	6.46	9.64	
Valproic Acid	µmol/l	1022	818	1226	Enzyme Immunoassay
	µg/ml	147	118	176	
	µmol/l	989	791	1187	Polarisation Fluoroimmunoassay
	µg/ml	143	114	172	
	µmol/l	1009	807	1211	Chemiluminescence
	µg/ml	146	116	176	
	µmol/l	880	704	1056	Turbidimetric
	µg/ml	127	102	152	

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DRUG CONTROL - LEVEL 3 (TDM CONTROL 3)

Cat. No. HD1669 **Lot No. 667DC** **Size: 20 x 5ml** **Expiry: 2017-12**

			Range		
Analyte	**unit**	**target**	**low**	**high**	**methods**
Vancomycin	µmol/l	20.8	16.6	25.0	Enzyme Immunoassay
	µg/ml	30.9	24.7	37.1	
	µmol/l	23.1	18.5	27.7	Polarisation Fluoroimmunoassay
	µg/ml	34.3	27.5	41.1	
	µmol/l	18.6	14.9	22.3	Chemiluminescence
	µg/ml	27.6	22.1	33.1	
	µmol/l	19.4	15.5	23.3	Turbidimetric
	µg/ml	28.8	23.0	34.6	