DRUG CONTROL - LEVEL 2 (TDM CONTROL 2)

Cat No. HD1668 **Lot No.** 664DC
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 2 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: (028) 9445 1070 or email Technical.Services@randox.com

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Cat. No. HD1668 Lot No. 664DC Size: 20 x 5ml Expiry: 2017-12

			Range		
Analyte	**unit**	**target**	**low**	**high**	**methods**
Amikacin	µmol/l	22.7	17.4	28.0	Enzyme Immunoassay
	µg/ml	13.3	10.2	16.4	
	µmol/l	22.6	18.1	27.1	Polarisation Fluoroimmunoassay
	µg/ml	13.2	10.6	15.8	
	µmol/l	22.0	17.6	26.4	KIMS
	µg/ml	12.9	10.3	15.5	
	µmol/l	23.5	18.8	28.2	Turbidimetric
	µg/ml	13.8	11.0	16.6	
Caffeine	µmol/l	38.5	28.9	48.1	Enzyme Immunoassay
	µg/ml	7.47	5.61	9.33	
Carbamazepine	µmol/l	38.8	31.0	46.6	Enzyme Immunoassay
	µg/ml	9.17	7.33	11.0	
	µmol/l	35.8	28.6	43.0	HPLC (Reverse Phase)
	µg/ml	8.46	6.76	10.2	
	µmol/l	37.3	29.8	44.8	Polarisation Fluoroimmunoassay
	µg/ml	8.82	7.04	10.6	
	µmol/l	28.3	22.6	34.0	Ortho Vitros Microslide Systems
	µg/ml	6.69	5.34	8.04	
	µmol/l	32.7	26.2	39.2	Chemiluminescence
	µg/ml	7.73	6.19	9.27	
	µmol/l	37.3	29.8	44.8	Turbidimetric
	µg/ml	8.82	7.04	10.6	
	µmol/l	39.4	31.5	47.3	Roche Integra
	µg/ml	9.31	7.45	11.2	
	µmol/l	35.0	28.0	42.0	KIMS
	µg/ml	8.27	6.62	9.92	
Cyclosporin	nmol/l	269	215	323	Chemiluminescence
	ng/ml	323	259	387	
Digoxin	nmol/l	1.73	1.38	2.08	Vitros
	ng/ml	1.35	1.08	1.62	
	nmol/l	2.13	1.70	2.56	Chemiluminescence
	ng/ml	1.66	1.33	1.99	
	nmol/l	1.98	1.58	2.38	Enzyme Immunoassay
	ng/ml	1.55	1.23	1.87	
	nmol/l	1.91	1.53	2.29	Polarisation Fluoroimmunoassay
	ng/ml	1.49	1.19	1.79	
	nmol/l	1.80	1.44	2.16	KIMS
	ng/ml	1.41	1.12	1.70	
	nmol/l	1.96	1.57	2.35	Turbidimetric
	ng/ml	1.53	1.23	1.83	
Ethosuximide	µmol/l	572	515	629	Enzyme Immunoassay
	µg/ml	81.1	73.0	89.2	

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DRUG CONTROL - LEVEL 2 (TDM CONTROL 2)

Cat. No. HD1668 Lot No. 664DC Size: 20 x 5ml Expiry: 2017-12

			Range		
Analyte	**unit**	**target**	**low**	**high**	**methods**
Ethosuximide	µmol/l	534	374	694	HPLC (Reverse Phase)
	µg/ml	75.7	53.0	98.4	
Gentamicin	µmol/l	11.0	8.80	13.2	Enzyme Immunoassay
	µg/ml	5.26	4.21	6.31	
	µmol/l	10.7	8.56	12.8	Polarisation Fluoroimmunoassay
	µg/ml	5.11	4.09	6.13	
	µmol/l	11.4	9.12	13.7	Chemiluminescence
	µg/ml	5.45	4.36	6.54	
	µmol/l	11.2	8.96	13.4	Turbidimetric
	µg/ml	5.35	4.28	6.42	
	µmol/l	8.74	6.99	10.5	KIMS
	µg/ml	4.18	3.34	5.02	
Lithium	mmol/l	1.16	1.02	1.30	Ion selective electrode
	mg/dl	0.806	0.708	0.904	
	mmol/l	1.16	1.02	1.30	Spectrophotometric
	mg/dl	0.806	0.708	0.904	
Lithium (Vitros)	mmol/l	1.63	1.30	1.96	Vitros
	mg/dl	1.13	0.903	1.36	
Methotrexate	µmol/l	1.25	0.931	1.57	Enzyme Immunoassay
	µg/ml	0.568	0.423	0.710	
	µmol/l	1.21	0.911	1.51	Polarisation Fluoroimmunoassay
	µg/ml	0.550	0.414	0.690	
Paracetamol	mmol/l	0.640	0.512	0.768	Vitros
	mg/l	96.8	77.5	116	
	mmol/l	0.520	0.416	0.624	Colorimetric
	mg/l	78.7	62.9	94.5	
	mmol/l	0.640	0.512	0.768	Polarisation Fluoroimmunoassay
	mg/l	96.8	77.5	116	
	mmol/l	0.550	0.440	0.660	Enzymatic
	mg/l	83.2	66.6	100	
	mmol/l	0.630	0.504	0.756	Turbidimetric
	mg/l	95.3	76.3	114	
Phenobarbital	µmol/l	122	97.6	146	Enzyme Immunoassay
	µg/ml	28.3	22.6	34.0	
	µmol/l	118	94.4	142	Polarisation Fluoroimmunoassay
	µg/ml	27.4	21.9	32.9	
	µmol/l	112	89.6	134	HPLC (Reverse Phase)
	µg/ml	26.0	20.8	31.2	
	µmol/l	122	97.6	146	Turbidimetric
	µg/ml	28.3	22.6	34.0	
	µmol/l	125	100	150	Chemiluminescence
	µg/ml	29.0	23.2	34.8	
	µmol/l	122	97.6	146	KIMS
	µg/ml	28.3	22.6	34.0	
Phenytoin	µmol/l	64.0	51.2	76.8	Vitros
	µg/ml	16.2	12.9	19.5	

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DRUG CONTROL - LEVEL 2 (TDM CONTROL 2)

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			Range		
Analyte	**unit**	**target**	**low**	**high**	**methods**
Phenytoin	µmol/l	68.0	54.4	81.6	Enzyme Immunoassay
	µg/ml	17.2	13.7	20.7	
	µmol/l	62.7	50.2	75.2	HPLC (Reverse Phase)
	µg/ml	15.8	12.7	18.9	
	µmol/l	66.6	53.3	79.9	Polarisation Fluoroimmunoassay
	µg/ml	16.8	13.5	20.1	
	µmol/l	67.4	53.9	80.9	Turbidimetric
	µg/ml	17.0	13.6	20.4	
	µmol/l	67.3	53.8	80.8	Chemiluminescence
	µg/ml	17.0	13.6	20.4	
	µmol/l	63.2	50.6	75.8	KIMS
	µg/ml	16.0	12.8	19.2	
Primidone	µmol/l	36.2	29.0	43.4	Polarisation Fluoroimmunoassay
	µg/ml	7.90	6.33	9.47	
Salicylic Acid	mmol/l	1.29	1.03	1.55	Vitros
	mg/dl	17.8	14.2	21.4	
	mmol/l	1.19	0.952	1.43	Colorimetric Trinder
	mg/dl	16.4	13.1	19.7	
	mmol/l	1.16	0.928	1.39	Enzymatic
	mg/dl	16.0	12.8	19.2	
Theophylline	µmol/l	92.8	74.2	111	Vitros
	µg/ml	16.7	13.4	20.0	
	µmol/l	89.1	71.3	107	Chemiluminescence
	µg/ml	16.1	12.8	19.4	
	µmol/l	91.8	73.4	110	Enzyme Immunoassay
	µg/ml	16.5	13.2	19.8	
	µmol/l	89.7	71.8	108	Polarisation Fluoroimmunoassay
	µg/ml	16.2	12.9	19.5	
	µmol/l	87.3	69.8	105	Turbidimetric
	µg/ml	15.7	12.6	18.8	
	µmol/l	87.6	70.1	105	KIMS
	µg/ml	15.8	12.6	19.0	
Tobramycin	µmol/l	10.6	8.48	12.7	Enzyme Immunoassay
	µg/ml	4.96	3.97	5.95	
	µmol/l	9.67	7.74	11.6	Polarisation Fluoroimmunoassay
	µg/ml	4.53	3.62	5.44	
	µmol/l	11.0	8.14	13.9	Turbidimetric
	µg/ml	5.15	3.81	6.49	
	µmol/l	11.6	9.28	13.9	Chemiluminescence
	µg/ml	5.43	4.34	6.52	
Valproic Acid	µmol/l	630	504	756	Enzyme Immunoassay
	µg/ml	90.9	72.7	109	
	µmol/l	578	462	694	Polarisation Fluoroimmunoassay
	µg/ml	83.4	66.7	100	
	µmol/l	592	474	710	Chemiluminescence
	µg/ml	85.4	68.4	102	

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			Range		
Analyte	**unit**	**target**	**low**	**high**	**methods**
Valproic Acid	µmol/l	545	436	654	Turbidimetric
	µg/ml	78.6	62.9	94.3	
Vancomycin	µmol/l	9.94	7.95	11.9	Enzyme Immunoassay
	µg/ml	14.8	11.8	17.8	
	µmol/l	10.6	8.48	12.7	Polarisation Fluoroimmunoassay
	µg/ml	15.7	12.6	18.8	
	µmol/l	9.07	7.21	10.9	Chemiluminescence
	µg/ml	13.5	10.7	16.3	
	µmol/l	9.34	7.47	11.2	Turbidimetric
	µg/ml	13.9	11.1	16.7	