

## DRUG CONTROL - LEVEL 2 (TDM CONTROL 2)

**CAT NO.** HD1668

**LOT NO.** 792DC

**SIZE:** 20 x 5ml

**EXPIRY:** 2022-02-28

**GTIN:** 05055273203585

### 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 +20°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 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  $\pm 2$  S.D.

If a method is unavailable, contact Randox Laboratories - Technical Services, Northern Ireland, tel: +44 (0) 028 9445 1070 or email [Technical.Services@randox.com](mailto:Technical.Services@randox.com).

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Analyte	unit	Target	Range		methods	
			low	high		
Amikacin	µmol/l	23.0	18.4	27.6	Enzyme Immunoassay	
	µg/ml	13.5	10.8	16.2		
	µmol/l	23.6	18.9	28.3	Polarisation Fluoroimmunoassay	
	µg/ml	13.8	11.1	16.5		
	µmol/l	22.7	18.2	27.2	KIMS	
	µg/ml	13.3	10.7	15.9		
Caffeine	µmol/l	24.9	19.9	29.9	Turbidimetric	
	µg/ml	14.6	11.7	17.5		
Caffeine	µmol/l	42.9	32.2	53.6	Enzyme Immunoassay	
	µg/ml	8.33	6.25	10.4		
Carbamazepine	µmol/l	40.6	32.5	48.7	Enzyme Immunoassay	
	µg/ml	9.60	7.68	11.5		
	µmol/l	36.9	29.5	44.3	Polarisation Fluoroimmunoassay	
	µg/ml	8.72	6.97	10.5		
	µmol/l	30.6	24.5	36.7	Ortho Vitros Microslide Systems	
	µg/ml	7.23	5.79	8.67		
	µmol/l	34.3	27.4	41.2	Chemiluminescence	
	µg/ml	8.11	6.48	9.74		
	µmol/l	33.8	27.0	40.6	Turbidimetric	
	µg/ml	7.99	6.38	9.60		
	µmol/l	36.0	28.8	43.2	KIMS	
	µg/ml	8.51	6.81	10.2		
Cyclosporin	nmol/l	239	191	287	Chemiluminescence	
	ng/ml	287	230	344		
Digoxin	nmol/l	1.81	1.45	2.17	Vitros	
	ng/ml	1.41	1.13	1.69		
	nmol/l	1.71	1.37	2.05	Chemiluminescence	
	ng/ml	1.34	1.07	1.61		
	nmol/l	1.80	1.44	2.16	Enzyme Immunoassay	
	ng/ml	1.41	1.12	1.70		
	nmol/l	1.79	1.43	2.15	KIMS	
	ng/ml	1.40	1.12	1.68		
	nmol/l	1.74	1.39	2.09	Turbidimetric	
	ng/ml	1.36	1.09	1.63		
	Ethosuximide	µmol/l	529	423	635	HPLC (Reverse Phase)
		µg/ml	75.0	60.0	90.0	
Gentamicin	µmol/l	11.0	8.80	13.2	Enzyme Immunoassay	
	µg/ml	5.26	4.21	6.31		
	µmol/l	10.3	8.24	12.4	Polarisation Fluoroimmunoassay	
	µg/ml	4.92	3.94	5.90		
	µmol/l	11.0	8.80	13.2	Chemiluminescence	
	µg/ml	5.26	4.21	6.31		

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Analyte	unit	Target	Range		methods
			low	high	
Gentamicin	µmol/l	12.7	10.2	15.2	Turbidimetric
	µg/ml	6.07	4.88	7.26	
	µmol/l	8.50	6.80	10.2	KIMS
	µg/ml	4.06	3.25	4.87	
Lithium	mmol/l	1.14	1.00	1.28	Ion selective electrode
	mg/dl	0.792	0.694	0.890	
	mmol/l	1.17	1.03	1.31	Spectrophotometric
	mg/dl	0.812	0.715	0.909	
Methotrexate	µmol/l	1.30	1.04	1.56	Enzyme Immunoassay
	µg/ml	0.591	0.473	0.709	
	µmol/l	1.26	1.01	1.51	Chemiluminescence
	µg/ml	0.573	0.459	0.687	
Paracetamol	mmol/l	0.620	0.496	0.744	Vitros
	mg/l	93.8	75.0	113	
	mmol/l	0.530	0.424	0.636	Colorimetric
	mg/l	80.2	64.2	96.2	
	mmol/l	0.560	0.448	0.672	Enzymatic
	mg/l	84.7	67.8	102	
	mmol/l	0.640	0.512	0.768	Turbidimetric
	mg/l	96.8	77.5	116	
Phenobarbital	mmol/l	0.620	0.496	0.744	Siemens Dimension Enzymatic
	mg/l	93.8	75.0	113	
	µmol/l	124	99.0	149	Enzyme Immunoassay
	µg/ml	28.8	23.0	34.6	
	µmol/l	114	91.2	137	Polarisation Fluoroimmunoassay
	µg/ml	26.4	21.2	31.6	
	µmol/l	121	96.8	145	Turbidimetric
	µg/ml	28.1	22.5	33.7	
Phenytoin	µmol/l	123	98.4	148	Chemiluminescence
	µg/ml	28.5	22.8	34.2	
	µmol/l	118	94.4	142	KIMS
	µg/ml	27.4	21.9	32.9	
	µmol/l	68.9	55.1	82.7	Vitros
	µg/ml	17.4	13.9	20.9	
	µmol/l	68.1	54.5	81.7	Enzyme Immunoassay
	µg/ml	17.2	13.8	20.6	
Primidone	µmol/l	66.4	53.1	79.7	Polarisation Fluoroimmunoassay
	µg/ml	16.8	13.4	20.2	
	µmol/l	64.3	51.4	77.2	Turbidimetric
	µg/ml	16.2	13.0	19.4	
	µmol/l	65.3	52.2	78.4	Chemiluminescence
	µg/ml	16.5	13.2	19.8	
	µmol/l	65.5	52.4	78.6	KIMS
	µg/ml	16.5	13.2	19.8	

## DRUG CONTROL - LEVEL 2 (TDM CONTROL 2)

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Analyte	unit	Target	Range		methods
			low	high	
Salicylic Acid	mmol/l	1.30	1.04	1.56	Vitros
	mg/dl	18.0	14.4	21.6	
	mmol/l	1.17	0.936	1.40	Colorimetric Trinder
	mg/dl	16.2	12.9	19.5	
	mmol/l	1.14	0.912	1.37	Enzymatic
	mg/dl	15.7	12.6	18.8	
Theophylline	µmol/l	83.3	66.6	100	Chemiluminescence
	µg/ml	15.0	12.0	18.0	
	µmol/l	90.5	72.4	109	Enzyme Immunoassay
	µg/ml	16.3	13.0	19.6	
	µmol/l	92.5	74.0	111	Polarisation Fluoroimmunoassay
	µg/ml	16.7	13.3	20.1	
	µmol/l	87.3	69.8	105	Turbidimetric
	µg/ml	15.7	12.6	18.8	
Tobramycin	µmol/l	10.4	8.32	12.5	Enzyme Immunoassay
	µg/ml	4.87	3.89	5.85	
	µmol/l	9.78	7.82	11.7	Polarisation Fluoroimmunoassay
	µg/ml	4.58	3.66	5.50	
	µmol/l	10.4	8.32	12.5	Turbidimetric
	µg/ml	4.87	3.89	5.85	
Valproic Acid	µmol/l	603	482	724	Enzyme Immunoassay
	µg/ml	87.0	69.6	104	
	µmol/l	566	453	679	Polarisation Fluoroimmunoassay
	µg/ml	81.7	65.4	98.0	
	µmol/l	564	451	677	Chemiluminescence
	µg/ml	81.4	65.1	97.7	
Vancomycin	µmol/l	550	440	660	Turbidimetric
	µg/ml	79.4	63.5	95.3	
	µmol/l	10.0	8.00	12.0	Enzyme Immunoassay
	µg/ml	14.9	11.9	17.9	
	µmol/l	11.5	9.20	13.8	Polarisation Fluoroimmunoassay
	µg/ml	17.1	13.7	20.5	
Vancomycin	µmol/l	10.5	8.40	12.6	Chemiluminescence
	µg/ml	15.6	12.5	18.7	
	µmol/l	10.3	8.24	12.4	Turbidimetric
	µg/ml	15.3	12.2	18.4	