DRUG CONTROL - LEVEL 2 (TDM CONTROL 2)

Cat No. HD1668 **Lot No.** 717DC
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 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 ±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	22.2	17.8	26.6	Enzyme Immunoassay
	µg/ml	13.0	10.4	15.6	
	µmol/l	22.9	18.3	27.5	Polarisation Fluoroimmunoassay
	µg/ml	13.4	10.7	16.1	
	µmol/l	22.3	17.8	26.8	KIMS
	µg/ml	13.1	10.4	15.8	
	µmol/l	23.5	18.8	28.2	Turbidimetric
	µg/ml	13.8	11.0	16.6	
Caffeine	µmol/l	38.7	29.0	48.4	Enzyme Immunoassay
	µg/ml	7.51	5.63	9.39	
Carbamazepine	µmol/l	37.2	29.8	44.6	Enzyme Immunoassay
	µg/ml	8.79	7.04	10.5	
	µmol/l	35.8	28.6	43.0	Polarisation Fluoroimmunoassay
	µg/ml	8.46	6.76	10.2	
	µmol/l	30.7	24.6	36.8	Ortho Vitros Microslide Systems
	µg/ml	7.26	5.82	8.70	
	µmol/l	31.8	25.4	38.2	Chemiluminescence
	µg/ml	7.52	6.00	9.04	
	µmol/l	36.3	29.0	43.6	Turbidimetric
	µg/ml	8.58	6.86	10.3	
	µmol/l	34.1	27.3	40.9	KIMS
	µg/ml	8.06	6.45	9.67	
Cyclosporin	nmol/l	259	207	311	Enzyme Immunoassay
	ng/ml	311	249	373	
	nmol/l	270	216	324	Chemiluminescence
	ng/ml	325	260	390	
Digoxin	nmol/l	1.87	1.50	2.24	Vitros
	ng/ml	1.46	1.17	1.75	
	nmol/l	1.91	1.53	2.29	Chemiluminescence
	ng/ml	1.49	1.19	1.79	
	nmol/l	1.97	1.58	2.36	Enzyme Immunoassay
	ng/ml	1.54	1.23	1.85	
	nmol/l	1.88	1.50	2.26	KIMS
	ng/ml	1.47	1.17	1.77	
	nmol/l	1.89	1.51	2.27	Turbidimetric
	ng/ml	1.48	1.18	1.78	
Ethosuximide	µmol/l	553	415	691	HPLC (Reverse Phase)
	µg/ml	78.4	58.8	98.0	
Gentamicin	µmol/l	11.3	9.04	13.6	Enzyme Immunoassay
	µg/ml	5.40	4.32	6.48	
	µmol/l	10.4	8.32	12.5	Polarisation Fluoroimmunoassay
	µg/ml	4.97	3.98	5.96	

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DRUG CONTROL - LEVEL 2 (TDM CONTROL 2)

Cat. No. HD1668 Lot No. 717DC Size: 20 x 5 ml Expiry: 2019-01

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Gentamicin	µmol/l	10.8	8.64	13.0	Chemiluminescence
	µg/ml	5.16	4.13	6.19	
	µmol/l	11.5	9.20	13.8	Turbidimetric
	µg/ml	5.50	4.40	6.60	
	µmol/l	8.40	6.72	10.1	KIMS
	µg/ml	4.02	3.21	4.83	
Lithium	mmol/l	1.09	0.959	1.22	Ion selective electrode
	mg/dl	0.757	0.666	0.848	
	mmol/l	1.14	1.00	1.28	Spectrophotometric
	mg/dl	0.792	0.694	0.890	
Lithium (Vitros)	mmol/l	1.55	1.24	1.86	Vitros
	mg/dl	1.08	0.861	1.30	
Methotrexate	µmol/l	1.15	0.920	1.38	Enzyme Immunoassay
	µg/ml	0.523	0.418	0.628	
	µmol/l	1.14	0.912	1.37	Polarisation Fluoroimmunoassay
	µg/ml	0.518	0.414	0.622	
Paracetamol	mmol/l	0.600	0.480	0.720	Vitros
	mg/l	90.8	72.6	109	
	mmol/l	0.495	0.396	0.594	Colorimetric
	mg/l	74.9	59.9	89.9	
	mmol/l	0.517	0.414	0.620	Enzymatic
	mg/l	78.2	62.6	93.8	
	mmol/l	0.598	0.478	0.718	Turbidimetric
	mg/l	90.5	72.3	109	
	mmol/l	0.616	0.493	0.739	Siemens Dimension Enzymatic
	mg/l	93.2	74.6	112	
Phenobarbital	µmol/l	117	93.6	140	Enzyme Immunoassay
	µg/ml	27.1	21.7	32.5	
	µmol/l	113	90.4	136	Polarisation Fluoroimmunoassay
	µg/ml	26.2	21.0	31.4	
	µmol/l	116	92.8	139	HPLC (Reverse Phase)
	µg/ml	26.9	21.5	32.3	
	µmol/l	118	94.4	142	Turbidimetric
	µg/ml	27.4	21.9	32.9	
	µmol/l	118	94.4	142	Chemiluminescence
	µg/ml	27.4	21.9	32.9	
	µmol/l	115	92.0	138	KIMS
	µg/ml	26.7	21.3	32.1	
Phenytoin	µmol/l	62.2	49.8	74.6	Vitros
	µg/ml	15.7	12.6	18.8	
	µmol/l	65.8	52.6	79.0	Enzyme Immunoassay
	µg/ml	16.6	13.3	19.9	
	µmol/l	68.5	54.8	82.2	HPLC (Reverse Phase)
	µg/ml	17.3	13.8	20.8	
	µmol/l	63.2	50.6	75.8	Polarisation Fluoroimmunoassay
	µg/ml	16.0	12.8	19.2	

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Analyte	**unit**	**Target**	**low**	**high**	**methods**
Phenytoin	µmol/l	65.2	52.2	78.2	Turbidimetric
	µg/ml	16.5	13.2	19.8	
	µmol/l	64.2	51.4	77.0	Chemiluminescence
	µg/ml	16.2	13.0	19.4	
	µmol/l	63.8	51.0	76.6	KIMS
	µg/ml	16.1	12.9	19.3	
Primidone	µmol/l	47.6	38.1	57.1	HPLC (Reverse Phase)
	µg/ml	10.4	8.32	12.5	
Salicylic Acid	mmol/l	1.28	1.02	1.54	Vitros
	mg/dl	17.7	14.1	21.3	
	mmol/l	1.06	0.848	1.27	Colorimetric Trinder
	mg/dl	14.6	11.7	17.5	
	mmol/l	1.11	0.888	1.33	Enzymatic
	mg/dl	15.3	12.3	18.3	
Theophylline	µmol/l	91.5	73.2	110	Vitros
	µg/ml	16.5	13.2	19.8	
	µmol/l	83.9	67.1	101	Chemiluminescence
	µg/ml	15.1	12.1	18.1	
	µmol/l	86.6	69.3	104	Enzyme Immunoassay
	µg/ml	15.6	12.5	18.7	
	µmol/l	88.5	70.8	106	Polarisation Fluoroimmunoassay
	µg/ml	15.9	12.8	19.0	
	µmol/l	84.1	67.3	101	Turbidimetric
	µg/ml	15.2	12.1	18.3	
	µmol/l	85.1	68.1	102	KIMS
	µg/ml	15.3	12.3	18.3	
Tobramycin	µmol/l	10.1	8.08	12.1	Enzyme Immunoassay
	µg/ml	4.73	3.78	5.68	
	µmol/l	9.40	7.52	11.3	Polarisation Fluoroimmunoassay
	µg/ml	4.40	3.52	5.28	
	µmol/l	10.2	8.16	12.2	Turbidimetric
	µg/ml	4.77	3.82	5.72	
	µmol/l	11.0	8.80	13.2	Chemiluminescence
	µg/ml	5.15	4.12	6.18	
Valproic Acid	µmol/l	581	465	697	Enzyme Immunoassay
	µg/ml	83.8	67.1	101	
	µmol/l	554	443	665	Polarisation Fluoroimmunoassay
	µg/ml	79.9	63.9	95.9	
	µmol/l	567	454	680	Chemiluminescence
	µg/ml	81.8	65.5	98.1	
	µmol/l	559	447	671	Turbidimetric
	µg/ml	80.7	64.5	96.9	
Vancomycin	µmol/l	10.8	8.64	13.0	Enzyme Immunoassay
	µg/ml	16.0	12.8	19.2	
	µmol/l	11.8	9.44	14.2	Polarisation Fluoroimmunoassay
	µg/ml	17.5	14.0	21.0	

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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Vancomycin	µmol/l	10.2	8.16	12.2	Chemiluminescence
	µg/ml	15.2	12.1	18.3	
	µmol/l	9.98	7.98	12.0	Turbidimetric
	µg/ml	14.8	11.9	17.7	

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