DRUG CONTROL (TDM CONTROL 1)

CAT NO.	HD1667	**LOT NO.**	911DC
SIZE:	20 x 5ml	**EXPIRY:**	2026-12-28
GTIN:	05055273203578		

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 to 8°C). Reconstituted serum is stable for 4 weeks at +2 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 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 1 20 x 5ml

MATERIALS REQUIRED BUT NOT PROVIDED
Volumetric Pipette

ASSIGNED VALUES
Due to the variation caused by test equipment, test reagents and laboratory technique, the quoted ranges are provided for guidance. It is recommended that these ranges are used until each laboratory has established its own ranges, based on individual laboratory requirements.

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 94451070 or email Technical.Services@randox.com

EC REP Randox Teoranta, Meenmore,
Dungloe, Donegal,
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28 Apr '23 me

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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Amikacin	µmol/l	7.07	5.66	8.48	KIMS
	µg/ml	4.14	3.31	4.97	
	µmol/l	6.24	4.99	7.49	Turbidimetric
	µg/ml	3.65	2.92	4.38	
Caffeine	µmol/l	12.9	9.68	16.1	Gravimetric
	µg/ml	2.50	1.88	3.13	
Carbamazepine	µmol/l	12.4	9.92	14.9	Enzyme Immunoassay
	µg/ml	2.93	2.35	3.51	
	µmol/l	11.6	9.28	13.9	Chemiluminescence
	µg/ml	2.74	2.19	3.29	
	µmol/l	12.2	9.76	14.6	Turbidimetric
	µg/ml	2.88	2.31	3.45	
	µmol/l	12.7	10.2	15.2	KIMS
	µg/ml	3.00	2.41	3.59	
Cyclosporin	nmol/l	92.0	73.6	110	Enzyme Immunoassay
	ng/ml	111	88.5	134	
	nmol/l	87.4	69.9	105	Chemiluminescence
	ng/ml	105	84.1	126	
Digoxin	nmol/l	0.626	0.500	0.750	Chemiluminescence
	ng/ml	0.490	0.390	0.590	
	nmol/l	0.692	0.550	0.830	Enzyme Immunoassay
	ng/ml	0.540	0.430	0.650	
	nmol/l	0.765	0.610	0.920	KIMS
	ng/ml	0.600	0.480	0.720	
	nmol/l	0.621	0.500	0.750	Turbidimetric
	ng/ml	0.490	0.390	0.590	
Ethosuximide	µmol/l	226	181	271	Gravimetric
	µg/ml	32.0	25.7	38.4	
Gentamicin	µmol/l	4.66	3.73	5.59	Enzyme Immunoassay
	µg/ml	2.23	1.78	2.68	
	µmol/l	4.75	3.80	5.70	Chemiluminescence
	µg/ml	2.27	1.82	2.72	
	µmol/l	4.88	3.90	5.86	Turbidimetric
	µg/ml	2.33	1.86	2.80	
	µmol/l	3.57	2.86	4.28	KIMS
	µg/ml	1.71	1.37	2.05	
	µmol/l	5.45	4.36	6.54	EMIT
	µg/ml	2.61	2.08	3.14	
Lithium	mmol/l	0.540	0.475	0.605	Spectrophotometric
	mg/dl	0.375	0.330	0.420	
Methotrexate	µmol/l	0.400	0.320	0.480	Enzyme Immunoassay
	µg/ml	0.182	0.145	0.219	

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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Methotrexate	µmol/l	0.360	0.288	0.432	Chemiluminescence
	µg/ml	0.164	0.131	0.197	
Paracetamol	mmol/l	0.170	0.136	0.204	Colorimetric
	mg/l	25.7	20.6	30.8	
	mmol/l	0.180	0.144	0.216	Enzymatic
	mg/l	27.2	21.8	32.6	
	mmol/l	0.200	0.160	0.240	Siemens Dimension Enzymatic
	mg/l	30.3	24.2	36.4	
	mmol/l	0.180	0.144	0.216	EMIT
	mg/l	27.2	21.8	32.6	
Phenobarbital	µmol/l	33.6	26.9	40.3	Enzyme Immunoassay
	µg/ml	7.80	6.24	9.36	
	µmol/l	33.0	26.4	39.6	Turbidimetric
	µg/ml	7.66	6.12	9.20	
	µmol/l	37.0	29.6	44.4	Chemiluminescence
	µg/ml	8.58	6.87	10.3	
	µmol/l	34.7	27.8	41.6	KIMS
	µg/ml	8.05	6.45	9.65	
	µmol/l	35.0	28.0	42.0	EMIT
	µg/ml	8.12	6.50	9.74	
Phenytoin	µmol/l	19.6	15.7	23.5	Enzyme Immunoassay
	µg/ml	4.95	3.96	5.94	
	µmol/l	20.4	16.3	24.5	Turbidimetric
	µg/ml	5.15	4.12	6.18	
	µmol/l	18.4	14.7	22.1	Chemiluminescence
	µg/ml	4.65	3.71	5.59	
	µmol/l	18.4	14.7	22.1	KIMS
	µg/ml	4.65	3.71	5.59	
Primidone	µmol/l	12.6	10.1	15.1	Gravimetric
	µg/ml	2.75	2.20	3.30	
Salicylic Acid	mmol/l	0.300	0.240	0.360	Colorimetric Trinder
	mg/dl	4.14	3.31	4.97	
	mmol/l	0.260	0.208	0.312	Enzymatic
	mg/dl	3.59	2.87	4.31	
	mmol/l	0.290	0.232	0.348	EMIT
	mg/dl	4.01	3.20	4.82	
	mmol/l	0.280	0.224	0.336	Spectrophotometric
	mg/dl	3.87	3.09	4.65	
Theophylline	µmol/l	27.8	22.2	33.4	Chemiluminescence
	µg/ml	5.01	4.00	6.02	
	µmol/l	30.1	24.1	36.1	Enzyme Immunoassay
	µg/ml	5.42	4.34	6.50	
	µmol/l	30.7	24.6	36.8	Turbidimetric
	µg/ml	5.53	4.43	6.63	
	µmol/l	29.6	23.7	35.5	KIMS
	µg/ml	5.33	4.27	6.39	

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Analyte	**unit**	**Target**	**low**	**high**	**methods**
Theophylline	µmol/l	28.9	23.1	34.7	EMIT
	µg/ml	5.21	4.16	6.26	
Tobramycin	µmol/l	4.23	3.38	5.08	Enzyme Immunoassay
	µg/ml	1.98	1.58	2.38	
	µmol/l	4.03	3.22	4.84	Turbidimetric
	µg/ml	1.89	1.51	2.27	
Valproic Acid	µmol/l	224	179	269	Enzyme Immunoassay
	µg/ml	32.3	25.8	38.8	
	µmol/l	215	172	258	Chemiluminescence
	µg/ml	31.0	24.8	37.2	
	µmol/l	218	174	262	Turbidimetric
	µg/ml	31.5	25.1	37.9	
Vancomycin	µmol/l	3.44	2.75	4.13	Enzyme Immunoassay
	µg/ml	5.11	4.09	6.13	
	µmol/l	3.41	2.73	4.09	Chemiluminescence
	µg/ml	5.07	4.06	6.08	
	µmol/l	3.38	2.70	4.06	Turbidimetric
	µg/ml	5.02	4.01	6.03	

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