

DRUG CONTROL - LEVEL I (TDM CONTROL I)

CAT NO.	HD1667	LOT NO.	791DC
SIZE:	20 x 5ml	EXPIRY:	2022-02-28
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.

- 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.
- Refer to the control section of the individual analyser application.
- Refrigerate any unused material. Prior to reuse, mix contents thoroughly.

MATERIALS PROVIDED

Drug Control Level I 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 94451070 or email Technical.Services@randox.com

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DRUG CONTROL LEVEL 1 (TDM CONTROL 1)

Cat. No. HD1667 Lot. No. 791DC Size 20 x 5ml Expiry 2022-02-28

Analyte	unit	Target	Range		methods
			low	high	
Amikacin	µmol/l	6.99	5.59	8.39	Enzyme Immunoassay
	µg/ml	4.09	3.27	4.91	
	µmol/l	6.68	5.34	8.02	Polarisation Fluoroimmunoassay
	µg/ml	3.91	3.13	4.69	
	µmol/l	6.31	5.05	7.57	KIMS
	µg/ml	3.70	2.96	4.44	
µmol/l	6.71	5.37	8.05	Turbidimetric	
µg/ml	3.93	3.14	4.72		
Caffeine	µmol/l	14.9	12.0	17.8	Enzyme Immunoassay
	µg/ml	2.89	2.33	3.45	
Carbamazepine	µmol/l	15.4	12.3	18.5	Enzyme Immunoassay
	µg/ml	3.64	2.91	4.37	
	µmol/l	13.4	10.7	16.1	Polarisation Fluoroimmunoassay
	µg/ml	3.17	2.53	3.81	
	µmol/l	11.2	8.96	13.4	Ortho Vitros Microslide Systems
	µg/ml	2.65	2.12	3.18	
	µmol/l	12.7	10.2	15.2	Chemiluminescence
	µg/ml	3.00	2.41	3.59	
	µmol/l	11.8	9.44	14.2	Turbidimetric
	µg/ml	2.79	2.23	3.35	
µmol/l	13.4	10.7	16.1	KIMS	
µg/ml	3.17	2.53	3.81		
Cyclosporin	nmol/l	87.5	70.0	105	Chemiluminescence
	ng/ml	105	84.2	126	
Digoxin	nmol/l	0.535	0.428	0.642	Chemiluminescence
	ng/ml	0.418	0.334	0.502	
	nmol/l	0.532	0.426	0.638	Enzyme Immunoassay
	ng/ml	0.415	0.333	0.497	
	nmol/l	0.646	0.517	0.775	KIMS
	ng/ml	0.505	0.404	0.606	
nmol/l	0.550	0.440	0.660	Turbidimetric	
ng/ml	0.430	0.344	0.516		
Ethosuximide	µmol/l	229	206	252	HPLC (Reverse Phase)
	µg/ml	32.5	29.2	35.8	
Gentamicin	µmol/l	4.52	3.62	5.42	Enzyme Immunoassay
	µg/ml	2.16	1.73	2.59	
	µmol/l	4.20	3.29	5.11	Polarisation Fluoroimmunoassay
	µg/ml	2.01	1.57	2.45	
	µmol/l	4.51	3.61	5.41	Chemiluminescence
	µg/ml	2.16	1.73	2.59	
µmol/l	5.00	4.00	6.00	Turbidimetric	
µg/ml	2.39	1.91	2.87		

DRUG CONTROL LEVEL 1 (TDM CONTROL 1)

Cat. No. HD1667 Lot. No. 791DC Size 20 x 5ml Expiry 2022-02-28

Analyte	unit	Target	Range		methods
			low	high	
Gentamicin	µmol/l	3.43	2.74	4.12	KIMS
	µg/ml	1.64	1.31	1.97	
Lithium	mmol/l	0.524	0.461	0.587	Ion selective electrode
	mg/dl	0.364	0.320	0.408	
	mmol/l	0.549	0.483	0.615	Spectrophotometric
	mg/dl	0.381	0.335	0.427	
Lithium (Vitros)	mmol/l	0.750	0.600	0.900	Vitros
	mg/dl	0.521	0.417	0.625	
Methotrexate	µmol/l	0.409	0.327	0.491	Enzyme Immunoassay
	µg/ml	0.186	0.149	0.223	
	µmol/l	0.400	0.320	0.480	Chemiluminescence
	µg/ml	0.182	0.145	0.219	
Paracetamol	mmol/l	0.190	0.152	0.228	Vitros
	mg/l	28.7	23.0	34.4	
	mmol/l	0.161	0.129	0.193	Colorimetric
	mg/l	24.4	19.5	29.3	
	mmol/l	0.177	0.142	0.212	Enzymatic
	mg/l	26.8	21.5	32.1	
	mmol/l	0.219	0.175	0.263	Turbidimetric
	mg/l	33.1	26.5	39.7	
	mmol/l	0.220	0.176	0.264	Siemens Dimension Enzymatic
	mg/l	33.3	26.6	40.0	
Phenobarbital	µmol/l	35.8	28.6	43.0	Enzyme Immunoassay
	µg/ml	8.31	6.64	9.98	
	µmol/l	33.8	27.0	40.6	Polarisation Fluoroimmunoassay
	µg/ml	7.84	6.26	9.42	
	µmol/l	34.4	27.5	41.3	Turbidimetric
	µg/ml	7.98	6.38	9.58	
	µmol/l	34.0	27.2	40.8	Chemiluminescence
	µg/ml	7.89	6.31	9.47	
µmol/l	33.1	26.5	39.7	KIMS	
µg/ml	7.68	6.15	9.21		
Phenytoin	µmol/l	20.1	16.1	24.1	Vitros
	µg/ml	5.08	4.07	6.09	
	µmol/l	19.6	15.7	23.5	Enzyme Immunoassay
	µg/ml	4.95	3.96	5.94	
	µmol/l	18.9	15.1	22.7	HPLC (Reverse Phase)
	µg/ml	4.77	3.81	5.73	
	µmol/l	19.2	15.4	23.0	Polarisation Fluoroimmunoassay
	µg/ml	4.85	3.89	5.81	
	µmol/l	19.4	15.5	23.3	Turbidimetric
	µg/ml	4.90	3.91	5.89	
	µmol/l	19.4	15.5	23.3	Chemiluminescence
	µg/ml	4.90	3.91	5.89	
µmol/l	18.7	15.0	22.4	KIMS	
µg/ml	4.72	3.79	5.65		

DRUG CONTROL LEVEL 1 (TDM CONTROL 1)

Cat. No. HD1667 Lot. No. 791DC Size 20 x 5ml Expiry 2022-02-28

Analyte	unit	Target	Range		methods
			low	high	
Primidone	µmol/l	13.6	10.9	16.3	Polarisation Fluoroimmunoassay
	µg/ml	2.97	2.38	3.56	
	µmol/l	12.1	9.68	14.5	HPLC (Reverse Phase)
	µg/ml	2.64	2.11	3.17	
Salicylic Acid	mmol/l	0.260	0.208	0.312	Colorimetric Trinder
	mg/dl	3.59	2.87	4.31	
	mmol/l	0.255	0.204	0.306	Enzymatic
	mg/dl	3.52	2.82	4.22	
Theophylline	µmol/l	28.8	23.0	34.6	Chemiluminescence
	µg/ml	5.19	4.14	6.24	
	µmol/l	30.4	24.3	36.5	Enzyme Immunoassay
	µg/ml	5.48	4.38	6.58	
	µmol/l	32.3	25.6	39.0	Polarisation Fluoroimmunoassay
	µg/ml	5.82	4.61	7.03	
	µmol/l	28.9	23.1	34.7	Turbidimetric
	µg/ml	5.21	4.16	6.26	
	µmol/l	29.2	23.4	35.0	KIMS
	µg/ml	5.26	4.22	6.30	
Tobramycin	µmol/l	3.72	2.98	4.46	Enzyme Immunoassay
	µg/ml	1.74	1.39	2.09	
	µmol/l	3.42	2.74	4.10	Polarisation Fluoroimmunoassay
	µg/ml	1.60	1.28	1.92	
	µmol/l	3.93	3.14	4.72	Turbidimetric
Valproic Acid	µg/ml	1.84	1.47	2.21	
	µmol/l	239	191	287	Enzyme Immunoassay
	µg/ml	34.5	27.6	41.4	
	µmol/l	219	175	263	Polarisation Fluoroimmunoassay
	µg/ml	31.6	25.3	37.9	
	µmol/l	217	174	260	Chemiluminescence
Vancomycin	µg/ml	31.3	25.1	37.5	
	µmol/l	222	178	266	Turbidimetric
	µg/ml	32.0	25.7	38.3	
	µmol/l	3.36	2.69	4.03	Enzyme Immunoassay
	µg/ml	4.99	4.00	5.98	
	µmol/l	4.15	3.32	4.98	Polarisation Fluoroimmunoassay
	µg/ml	6.17	4.93	7.41	
	µmol/l	3.21	2.57	3.85	Chemiluminescence
	µg/ml	4.77	3.82	5.72	
	µmol/l	3.20	2.56	3.84	Turbidimetric
µg/ml	4.75	3.80	5.70		