

DRUG CONTROL - LEVEL I (TDM CONTROL I)

Cat No. HD1667 **Lot No.** 650DC
Size: 20 x 5ml **Expiry:** 2017-05

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 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 9445 1070 or email Technical.Services@randox.com

05 Feb '14 ne

DRUG CONTROL - LEVEL 1 (TDM CONTROL 1)

Cat. No. HD1667 Lot No. 650DC Size: 20 x 5ml Expiry: 2017-05

Range					
Analyte	unit	target	low	high	methods
Amikacin	µmol/l	6.55	5.24	7.86	Enzyme Immunoassay
	µg/ml	3.84	3.07	4.61	
	µmol/l	6.44	5.15	7.73	Polarisation Fluoroimmunoassay
	µg/ml	3.77	3.02	4.52	
	µmol/l	6.35	5.08	7.62	KIMS
	µg/ml	3.72	2.97	4.47	
	µmol/l	6.12	4.90	7.34	Turbidimetric
	µg/ml	3.58	2.87	4.29	
Caffeine	µmol/l	13.8	10.4	17.3	Enzyme Immunoassay
	µg/ml	2.68	2.02	3.34	
Carbamazepine	µmol/l	14.1	11.3	16.9	Enzyme Immunoassay
	µg/ml	3.33	2.67	3.99	HPLC (Reverse Phase)
	µmol/l	14.6	11.7	17.5	
	µg/ml	3.45	2.77	4.13	
	µmol/l	13.4	10.7	16.1	Polarisation Fluoroimmunoassay
	µg/ml	3.17	2.53	3.81	Chemiluminescence
	µmol/l	12.6	10.1	15.1	
	µg/ml	2.98	2.39	3.57	Turbidimetric
	µmol/l	12.4	9.92	14.9	
	µg/ml	2.93	2.35	3.51	Roche Integra
	µmol/l	13.2	10.6	15.8	
	µg/ml	3.12	2.51	3.73	KIMS
	µmol/l	12.2	9.76	14.6	
	µg/ml	2.88	2.31	3.45	
Cyclosporin	nmol/l	62.1	49.7	74.5	Enzyme Immunoassay
	ng/ml	74.7	59.8	89.6	
	nmol/l	59.5	47.6	71.4	Chemiluminescence
	ng/ml	71.6	57.2	86.0	
Digoxin	nmol/l	0.639	0.511	0.767	Vitros
	ng/ml	0.499	0.399	0.599	
	nmol/l	0.624	0.499	0.749	Chemiluminescence
	ng/ml	0.487	0.390	0.584	
	nmol/l	0.655	0.524	0.786	Enzyme Immunoassay
	ng/ml	0.512	0.409	0.615	
	nmol/l	0.702	0.562	0.842	Polarisation Fluoroimmunoassay
	ng/ml	0.548	0.439	0.657	
Ethosuximide	nmol/l	0.639	0.511	0.767	KIMS
	ng/ml	0.499	0.399	0.599	
	nmol/l	0.620	0.496	0.744	Turbidimetric
	ng/ml	0.484	0.387	0.581	
	µmol/l	204	153	255	HPLC (Reverse Phase)
	µg/ml	28.9	21.7	36.1	

DRUG CONTROL - LEVEL 1 (TDM CONTROL 1)

Cat. No. HD1667 Lot No. 650DC Size: 20 x 5ml Expiry: 2017-05

Range					
Analyte	unit	target	low	high	methods
Gentamicin	µmol/l	4.50	3.60	5.40	Enzyme Immunoassay
	µg/ml	2.15	1.72	2.58	
	µmol/l	4.67	3.74	5.60	Polarisation Fluoroimmunoassay
	µg/ml	2.23	1.79	2.67	
	µmol/l	4.48	3.58	5.38	Chemiluminescence
	µg/ml	2.14	1.71	2.57	
	µmol/l	4.69	3.75	5.63	Turbidimetric
	µg/ml	2.24	1.79	2.69	
Lithium	µmol/l	3.75	3.00	4.50	KIMS
	µg/ml	1.79	1.43	2.15	
	mmol/l	0.409	0.360	0.458	Ion selective electrode
	mg/dl	0.284	0.250	0.318	
Lithium	mmol/l	0.441	0.388	0.494	Spectrophotometric
	mg/dl	0.306	0.269	0.343	
	mmol/l	0.663	0.530	0.796	Vitros
	mg/dl	0.460	0.368	0.552	
Methotrexate	µmol/l	0.338	0.270	0.406	Enzyme Immunoassay
	µg/ml	0.154	0.123	0.185	
	µmol/l	0.335	0.268	0.402	Polarisation Fluoroimmunoassay
	µg/ml	0.152	0.122	0.182	
Paracetamol	mmol/l	0.162	0.130	0.194	Vitros
	mg/l	24.5	19.7	29.3	
	mmol/l	0.174	0.139	0.209	Polarisation Fluoroimmunoassay
	mg/l	26.3	21.0	31.6	
	mmol/l	0.144	0.115	0.173	Enzymatic
	mg/l	21.8	17.4	26.2	
	mmol/l	0.156	0.125	0.187	Turbidimetric
	mg/l	23.6	18.9	28.3	
Phenobarbital	µmol/l	32.1	25.7	38.5	Enzyme Immunoassay
	µg/ml	7.45	5.96	8.94	
	µmol/l	32.7	26.2	39.2	Polarisation Fluoroimmunoassay
	µg/ml	7.59	6.08	9.10	
	µmol/l	39.0	31.2	46.8	HPLC (Reverse Phase)
	µg/ml	9.05	7.24	10.9	
	µmol/l	34.2	27.4	41.0	Turbidimetric
	µg/ml	7.93	6.36	9.50	
Phenytoin	µmol/l	35.2	28.2	42.2	Chemiluminescence
	µg/ml	8.17	6.54	9.80	
	µmol/l	33.7	27.0	40.4	KIMS
	µg/ml	7.82	6.26	9.38	
	µmol/l	14.9	11.9	17.9	Vitros
	µg/ml	3.76	3.00	4.52	
	µmol/l	17.6	14.1	21.1	Enzyme Immunoassay
	µg/ml	4.44	3.56	5.32	
Phenytoin	µmol/l	17.6	14.1	21.1	HPLC (Reverse Phase)
	µg/ml	4.44	3.56	5.32	

DRUG CONTROL - LEVEL 1 (TDM CONTROL 1)

Cat. No. HD1667 Lot No. 650DC Size: 20 x 5ml Expiry: 2017-05

Range					
Analyte	unit	target	low	high	methods
Phenytoin	µmol/l	16.9	13.5	20.3	Polarisation Fluoroimmunoassay
	µg/ml	4.27	3.41	5.13	
	µmol/l	16.8	13.4	20.2	Turbidimetric
	µg/ml	4.24	3.38	5.10	
	µmol/l	18.4	14.7	22.1	Chemiluminescence
	µg/ml	4.65	3.71	5.59	
	µmol/l	16.3	13.0	19.6	KIMS
	µg/ml	4.12	3.28	4.96	
Primidone	µmol/l	12.4	9.92	14.9	Polarisation Fluoroimmunoassay
	µg/ml	2.71	2.17	3.25	
Salicylic Acid	mmol/l	0.310	0.248	0.372	Vitros
	mg/dl	4.28	3.43	5.13	
	mmol/l	0.270	0.216	0.324	Colorimetric Trinder
	mg/dl	3.73	2.98	4.48	
	mmol/l	0.252	0.202	0.302	Enzymatic
	mg/dl	3.48	2.79	4.17	
Theophylline	µmol/l	24.6	19.7	29.5	Vitros
	µg/ml	4.43	3.55	5.31	
	µmol/l	26.2	21.0	31.4	Chemiluminescence
	µg/ml	4.72	3.78	5.66	
	µmol/l	26.6	21.3	31.9	Enzyme Immunoassay
	µg/ml	4.79	3.84	5.74	
	µmol/l	27.5	22.0	33.0	Polarisation Fluoroimmunoassay
	µg/ml	4.96	3.96	5.96	
	µmol/l	23.9	19.1	28.7	HPLC (Reverse Phase)
	µg/ml	4.31	3.44	5.18	
	µmol/l	25.5	20.4	30.6	Turbidimetric
	µg/ml	4.60	3.68	5.52	
Tobramycin	µmol/l	25.5	20.4	30.6	KIMS
	µg/ml	4.60	3.68	5.52	
	µmol/l	4.19	3.35	5.03	Enzyme Immunoassay
	µg/ml	1.96	1.57	2.35	
	µmol/l	4.03	3.22	4.84	Polarisation Fluoroimmunoassay
	µg/ml	1.89	1.51	2.27	
	µmol/l	4.29	3.43	5.15	Turbidimetric
	µg/ml	2.01	1.61	2.41	
Valproic Acid	µmol/l	4.71	3.77	5.65	Chemiluminescence
	µg/ml	2.20	1.76	2.64	
	µmol/l	199	159	239	Enzyme Immunoassay
	µg/ml	28.7	22.9	34.5	
	µmol/l	189	151	227	Polarisation Fluoroimmunoassay
	µg/ml	27.3	21.8	32.8	
	µmol/l	197	158	236	Chemiluminescence
	µg/ml	28.4	22.8	34.0	
	µmol/l	184	147	221	Turbidimetric
	µg/ml	26.6	21.2	32.0	

%

DRUG CONTROL - LEVEL 1 (TDM CONTROL 1)

Cat. No. HD1667 Lot No. 650DC Size: 20 x 5ml Expiry: 2017-05

Range					
Analyte	unit	target	low	high	methods
Vancomycin	µmol/l	3.75	3.00	4.50	Enzyme Immunoassay
	µg/ml	5.57	4.46	6.68	
	µmol/l	4.32	3.46	5.18	Polarisation Fluoroimmunoassay
	µg/ml	6.42	5.14	7.70	
	µmol/l	3.31	2.65	3.97	Chemiluminescence
	µg/ml	4.92	3.94	5.90	
	µmol/l	3.34	2.67	4.01	Turbidimetric
	µg/ml	4.96	3.97	5.95	