

DRUG CONTROL - LEVEL I (TDM CONTROL I)

Cat No. HD1667 **Lot No.** 636DC
Size: 20 x 5ml **Expiry:** 2016-11

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.

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

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DRUG CONTROL - LEVEL 1 (TDM CONTROL 1)

Cat. No. HD1667 Lot No. 636DC Size: 20 x 5ml Expiry: 2016-11

Range					
Analyte	unit	target	low	high	methods
Amikacin	µmol/l	6.63	5.30	7.96	Enzyme Immunoassay
	µg/ml	3.88	3.10	4.66	
	µmol/l	6.62	5.30	7.94	Polarisation Fluoroimmunoassay
	µg/ml	3.88	3.10	4.66	
	µmol/l	6.39	5.11	7.67	KIMS
	µg/ml	3.74	2.99	4.49	
	µmol/l	6.43	5.14	7.72	Turbidimetric
	µg/ml	3.77	3.01	4.53	
Caffeine	µmol/l	13.2	9.90	16.5	Enzyme Immunoassay
	µg/ml	2.56	1.92	3.20	
Carbamazepine	µmol/l	14.2	11.4	17.0	Enzyme Immunoassay
	µg/ml	3.36	2.69	4.03	
	µmol/l	13.2	10.6	15.8	HPLC (Reverse Phase)
	µg/ml	3.12	2.51	3.73	
	µmol/l	13.6	10.9	16.3	Polarisation Fluoroimmunoassay
	µg/ml	3.22	2.58	3.86	
	µmol/l	12.2	9.76	14.6	Chemiluminescence
	µg/ml	2.88	2.31	3.45	
	µmol/l	12.5	10.0	15.0	Turbidimetric
	µg/ml	2.96	2.36	3.56	
Cyclosporin	µmol/l	13.2	10.6	15.8	Roche Integra
	µg/ml	3.12	2.51	3.73	
	µmol/l	12.6	10.1	15.1	KIMS
	µg/ml	2.98	2.39	3.57	
	nmol/l	73.6	58.9	88.3	Enzyme Immunoassay
	ng/ml	88.5	70.8	106	
	nmol/l	59.1	47.3	70.9	Polarisation Fluoroimmunoassay
	ng/ml	71.1	56.9	85.3	
Digoxin	nmol/l	88.5	70.8	106	Chemiluminescence
	ng/ml	106	85.1	127	
	nmol/l	0.673	0.538	0.808	Vitros
	ng/ml	0.526	0.420	0.632	
	nmol/l	0.625	0.500	0.750	Chemiluminescence
	ng/ml	0.488	0.391	0.585	
	nmol/l	0.651	0.521	0.781	Enzyme Immunoassay
	ng/ml	0.508	0.407	0.609	
	nmol/l	0.614	0.491	0.737	Polarisation Fluoroimmunoassay
	ng/ml	0.480	0.383	0.577	
	nmol/l	0.652	0.522	0.782	KIMS
	ng/ml	0.509	0.408	0.610	
	nmol/l	0.666	0.533	0.799	Turbidimetric
	ng/ml	0.520	0.416	0.624	

DRUG CONTROL - LEVEL 1 (TDM CONTROL 1)

Cat. No. HD1667 Lot No. 636DC Size: 20 x 5ml Expiry: 2016-11

Range					
Analyte	unit	target	low	high	methods
Ethosuximide	µmol/l	267	214	320	Enzyme Immunoassay
	µg/ml	37.9	30.3	45.5	
	µmol/l	223	178	268	HPLC (Reverse Phase)
	µg/ml	31.6	25.2	38.0	
Gentamicin	µmol/l	4.57	3.66	5.48	Enzyme Immunoassay
	µg/ml	2.18	1.75	2.61	
	µmol/l	4.58	3.66	5.50	Polarisation Fluoroimmunoassay
	µg/ml	2.19	1.75	2.63	
	µmol/l	4.64	3.71	5.57	Chemiluminescence
	µg/ml	2.22	1.77	2.67	
	µmol/l	4.61	3.69	5.53	Turbidimetric
	µg/ml	2.20	1.76	2.64	
Lithium	µmol/l	3.58	2.86	4.30	KIMS
	µg/ml	1.71	1.37	2.05	
	mmol/l	0.672	0.538	0.806	Vitros
	mg/dl	0.467	0.374	0.560	
	mmol/l	0.444	0.355	0.533	Ion selective electrode
	mg/dl	0.308	0.247	0.369	
	mmol/l	0.474	0.379	0.569	Spectrophotometric
	mg/dl	0.329	0.263	0.395	
Methotrexate	µmol/l	0.356	0.285	0.427	Enzyme Immunoassay
	µg/ml	0.162	0.130	0.194	
	µmol/l	0.348	0.278	0.418	Polarisation Fluoroimmunoassay
	µg/ml	0.158	0.126	0.190	
Paracetamol	mmol/l	0.172	0.138	0.206	Vitros
	mg/l	26.0	20.9	31.1	
	mmol/l	0.174	0.139	0.209	Polarisation Fluoroimmunoassay
	mg/l	26.3	21.0	31.6	
	mmol/l	0.155	0.124	0.186	Enzymatic
	mg/l	23.5	18.8	28.2	
	mmol/l	0.166	0.133	0.199	Turbidimetric
	mg/l	25.1	20.1	30.1	
Phenobarbital	µmol/l	33.4	26.7	40.1	Enzyme Immunoassay
	µg/ml	7.75	6.19	9.31	
	µmol/l	33.8	27.0	40.6	Polarisation Fluoroimmunoassay
	µg/ml	7.84	6.26	9.42	
	µmol/l	31.7	25.4	38.0	HPLC (Reverse Phase)
	µg/ml	7.35	5.89	8.81	
	µmol/l	32.3	25.8	38.8	Vitros
	µg/ml	7.49	5.99	8.99	
	µmol/l	35.3	28.2	42.4	Turbidimetric
	µg/ml	8.19	6.54	9.84	
	µmol/l	36.2	29.0	43.4	Chemiluminescence
	µg/ml	8.40	6.73	10.1	
	µmol/l	34.7	27.8	41.6	KIMS
	µg/ml	8.05	6.45	9.65	

DRUG CONTROL - LEVEL 1 (TDM CONTROL 1)

Cat. No. HD1667 Lot No. 636DC Size: 20 x 5ml Expiry: 2016-11

Range					
Analyte	unit	target	low	high	methods
Phenytoin	µmol/l	17.9	14.3	21.5	Vitros
	µg/ml	4.52	3.61	5.43	
	µmol/l	17.9	14.3	21.5	Enzyme Immunoassay
	µg/ml	4.52	3.61	5.43	
	µmol/l	16.8	13.4	20.2	HPLC (Reverse Phase)
	µg/ml	4.24	3.38	5.10	
	µmol/l	17.7	14.2	21.2	Polarisation Fluoroimmunoassay
	µg/ml	4.47	3.59	5.35	
	µmol/l	17.5	14.0	21.0	Turbidimetric
	µg/ml	4.42	3.54	5.30	
Primidone	µmol/l	18.7	15.0	22.4	Chemiluminescence
	µg/ml	4.72	3.79	5.65	
	µmol/l	16.8	13.4	20.2	KIMS
	µg/ml	4.24	3.38	5.10	
Salicylic Acid	µmol/l	12.9	10.3	15.5	Polarisation Fluoroimmunoassay
	µg/ml	2.82	2.25	3.39	
	µmol/l	17.8	14.2	21.4	HPLC (Reverse Phase)
	µg/ml	3.89	3.10	4.68	
Theophylline	mmol/l	0.320	0.256	0.384	Vitros
	mg/dl	4.42	3.54	5.30	
	mmol/l	0.276	0.221	0.331	Colorimetric Trinder
	mg/dl	3.81	3.05	4.57	
	mmol/l	0.264	0.211	0.317	Polarisation Fluoroimmunoassay
	mg/dl	3.65	2.91	4.39	
Tobramycin	mmol/l	0.267	0.214	0.320	Enzymatic
	mg/dl	3.69	2.96	4.42	
	µmol/l	25.1	20.1	30.1	Vitros
	µg/ml	4.52	3.62	5.42	
	µmol/l	27.4	21.9	32.9	Chemiluminescence
	µg/ml	4.94	3.95	5.93	
	µmol/l	27.9	22.3	33.5	Enzyme Immunoassay
	µg/ml	5.03	4.02	6.04	
	µmol/l	28.5	22.8	34.2	Polarisation Fluoroimmunoassay
	µg/ml	5.14	4.11	6.17	
Tobramycin	µmol/l	26.4	21.1	31.7	Turbidimetric
	µg/ml	4.76	3.80	5.72	
	µmol/l	27.2	21.8	32.6	KIMS
	µg/ml	4.90	3.93	5.87	
	µmol/l	4.40	3.52	5.28	Enzyme Immunoassay
	µg/ml	2.06	1.65	2.47	
	µmol/l	4.02	3.22	4.82	Polarisation Fluoroimmunoassay
	µg/ml	1.88	1.51	2.25	
Tobramycin	µmol/l	4.58	3.66	5.50	Turbidimetric
	µg/ml	2.14	1.71	2.57	
	µmol/l	4.60	3.68	5.52	Chemiluminescence
	µg/ml	2.15	1.72	2.58	

DRUG CONTROL - LEVEL 1 (TDM CONTROL 1)

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Range					
Analyte	unit	target	low	high	methods
Valproic Acid	µmol/l	211	169	253	Enzyme Immunoassay
	µg/ml	30.4	24.4	36.4	
	µmol/l	200	160	240	Polarisation Fluoroimmunoassay
	µg/ml	28.9	23.1	34.7	
	µmol/l	203	162	244	Chemiluminescence
	µg/ml	29.3	23.4	35.2	
Vancomycin	µmol/l	192	154	230	Turbidimetric
	µg/ml	27.7	22.2	33.2	
	µmol/l	3.56	2.85	4.27	Enzyme Immunoassay
	µg/ml	5.29	4.23	6.35	
	µmol/l	4.11	3.29	4.93	Polarisation Fluoroimmunoassay
	µg/ml	6.11	4.89	7.33	
	µmol/l	3.19	2.55	3.83	Chemiluminescence
	µg/ml	4.74	3.79	5.69	
	µmol/l	3.24	2.59	3.89	Turbidimetric
	µg/ml	4.81	3.85	5.77	