

DRUG CONTROL (TDM CONTROL 3)

CAT NO.	HD1669	LOT NO.	916DC
SIZE:	20 x 5ml	EXPIRY:	2026-12-28
GTIN:	05055273203592		

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 I, 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 $(+2^{\circ}C \text{ to } +8^{\circ}C)$. Reconstituted serum is stable for 4 weeks at $+2^{\circ}C$ to $+8^{\circ}C$ 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 3 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 9445 1070 or email Technical.Services@randox.com

EC REP Randox Teoranta, Meenmore, Dungloe, Donegal, F94 TV06, Ireland

28 Apr '23 me

RANDOX

DRUG CONTROL LEVEL 3 (TDM CONTROL 3)

Cat. No. HD1669 Lot. No. 916DC Size 20 x 5ml Expiry 2026-12-28					
			Rai	nge	
Analyte	unit	Target	low	high	methods
Amikacin	µmol/l	48.0	38.4	57.6	KIMS
	µg/ml	28.1	22.5	33.7	
	µmol/l	49.1	39.3	58.9	Turbidimetric
	µg/ml	28.8	23.0	34.6	
Caffeine	µmol/l	72.0	54.0	90.0	Gravimetric
	µg/ml	14.0	10.5	17.5	
Carbamazepine	µmol/l	66.1	52.9	79.3	Enzyme Immunoassay
	µg/ml	15.6	12.5	18.7	
	µmol/l	61.1	48.9	73.3	Chemiluminescence
	µg/ml	14.4	11.6	17.2	
	µmol/l	58.2	46.6	69.8	Turbidimetric
	µg/ml	13.8	11.0	16.6	
	µmol/l	67.2	53.8	80.6	KIMS
	µg/ml	15.9	12.7	19.1	
Cyclosporin	nmol/l	537	430	644	Enzyme Immunoassay
	ng/ml	646	517	775	
	nmol/l	511	409	613	Chemiluminescence
	ng/ml	615	492	738	
Digoxin	nmol/l	3.82	3.06	4.58	Chemiluminescence
	ng/ml	2.98	2.39	3.58	
	nmol/l	3.95	3.16	4.74	Enzyme Immunoassay
	ng/ml	3.08	2.47	3.70	
	nmol/l	3.91	3.13	4.69	KIMS
	ng/ml	3.05	2.44	3.66	
	nmol/l	3.96	3.17	4.75	Turbidimetric
	ng/ml	3.09	2.48	3.71	
Ethosuximide	µmol/l	890	712	1068	Gravimetric
	µg/ml	126	101	151	
Gentamicin	µmol/l	16.9	13.5	20.3	Enzyme Immunoassay
	µg/ml	8.08	6.45	9.71	
	µmol/l	18.0	14.4	21.6	Chemiluminescence
	µg/ml	8.60	6.88	10.3	
	µmol/l	17.2	13.8	20.6	Turbidimetric
	µg/ml	8.22	6.60	9.84	
	µmol/l	11.7	9.36	14.0	KIMS
	µg/ml	5.59	4.47	6.71	
	µmol/l	18.7	15.0	22.4	EMIT
	µg/ml	8.94	7.17	10.7	
Lithium	mmol/l	1.78	1.57	1.99	Spectrophotometric
	mg/dl	1.24	1.09	1.39	
Methotrexate	µmol/l	9.30	7.44	11.2	Enzyme Immunoassay
	µg/ml	4.23	3.38	5.08	

RANDOX

DRUG CONTROL LEVEL 3 (TDM CONTROL 3)

Cat. No. HD1669 Lot. No. 916DC Size 20 x 5ml Expiry 2026-12-28						
Range						
Analyte	unit	Target	low	high	methods	
Methotrexate Paracetamol	µmol/l	7.85	6.28	9.42	Chemiluminescence	
	µg/ml	3.57	2.85	4.29		
	mmol/l	1.26	1.01	1.51	Colorimetric	
	mg/l	191	153	229		
	mmol/l	1.36	1.09	1.63	Enzymatic	
	mg/l	206	165	247		
	mmol/l	1.30	1.04	1.56	EMIT	
	mg/l	197	157	237		
Phenobarbital	µmol/l	216	173	259	Enzyme Immunoassay	
	µg/ml	50.1	40.1	60.1		
	µmol/l	210	168	252	Turbidimetric	
	µg/ml	48.7	39.0	58.4		
	µmol/l	218	174	262	Chemiluminescence	
	µg/ml	50.6	40.4	60.8		
	µmol/l	210	168	252	KIMS	
	µg/ml	48.7	39.0	58.4		
	µmol/l	214	171	257	EMIT	
	µg/ml	49.6	39.7	59.5		
Phenytoin	µmol/l	96.1	76.9	115	Enzyme Immunoassay	
	µg/ml	24.3	19.4	29.2		
	µmol/l	97.7	78.2	117	Turbidimetric	
	µg/ml	24.7	19.7	29.7		
	µmol/l	87.9	70.3	105	Chemiluminescence	
	µg/ml	22.2	17.8	26.6		
	µmol/l	93.1	74.5	112	KIMS	
	µg/ml	23.5	18.8	28.2		
Primidone	µmol/l	55.0	44.0	66.0	Gravimetric	
	µg/ml	12.0	9.61	14.4		
Salicylic Acid	mmol/l	2.86	2.29	3.43	Colorimetric Trinder	
	mg/dl	39.5	31.6	47.4		
	mmol/l	2.77	2.22	3.32	Enzymatic	
	mg/dl	38.3	30.7	45.9		
	mmol/l	2.83	2.26	3.40	EMIT	
	mg/dl	39.1	31.2	47.0		
	mmol/l	2.72	2.18	3.26	Spectrophotometric	
	mg/dl	37.6	30.1	45.1		
Theophylline	µmol/l	163	130	196	Chemiluminescence	
	µg/ml	29.4	23.4	35.4		
	µmol/l	175	140	210	Enzyme Immunoassay	
	µg/ml	31.5	25.2	37.8		
	µmol/l	167	134	200	Turbidimetric	
	µg/ml	30.1	24.1	36.1		
	µmol/l	174	139	209	KIMS	
	µg/ml	31.4	25.0	37.8		
	µmol/l	159	127	191	EMIT	
	µg/ml	28.7	22.9	34.5		

RANDOX

DRUG CONTROL LEVEL 3 (TDM CONTROL 3)

Cat. No. HD1669	Lot. No. 916DC		Size 2	0 x 5ml Ex	xpiry 2026-12-28	
Range						
Analyte	unit	Target	low	high	methods	
Tobramycin	µmol/l	17.9	14.3	21.5	Enzyme Immunoassay	
	µg/ml	8.38	6.69	10.1		
	µmol/l	16.7	13.4	20.0	Turbidimetric	
	µg/ml	7.82	6.27	9.37		
Valproic Acid	µmol/l	951	761	1141	Enzyme Immunoassay	
	µg/ml	137	110	164		
	µmol/l	987	790	1184	Chemiluminescence	
	µg/ml	142	114	170		
	µmol/l	969	775	1163	Turbidimetric	
	µg/ml	140	112	168		
Vancomycin	µmol/l	18.8	15.0	22.6	Enzyme Immunoassay	
	µg/ml	27.9	22.3	33.5		
	µmol/l	21.3	17.0	25.6	Chemiluminescence	
	µg/ml	31.6	25.3	37.9		
	µmol/l	20.0	16.0	24.0	Turbidimetric	
	µg/ml	29.7	23.8	35.6		