PRODUCT INFORMATION

HD1669

822DC

Please note that while Caffeine, Ethosuximide and Primidone are present in 822DC – Drug Control Level 3, targets and ranges are not provided for these analytes.

CCS6459

DRUG CONTROL (TDM CONTROL 3)

CAT NO.	HD1669	**LOT NO.**	822DC
SIZE:	20 x 5ml	**EXPIRY:**	2023-01-28
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 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 3 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 3 (TDM CONTROL 3)

Cat. No. HD1669 Lot. No. 822DC Size 12 x 5ml Expiry 2023-01-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Amikacin	µmol/l	49.5	39.6	59.4	Enzyme Immunoassay
	µg/ml	29.0	23.2	34.8	
	µmol/l	49.8	39.8	59.8	Polarisation Fluoroimmunoassay
	µg/ml	29.2	23.3	35.1	
	µmol/l	50.2	40.2	60.2	KIMS
	µg/ml	29.4	23.5	35.3	
	µmol/l	51.9	41.5	62.3	Turbidimetric
	µg/ml	30.4	24.3	36.5	
Carbamazepine	µmol/l	75.0	60.0	90.0	Enzyme Immunoassay
	µg/ml	17.7	14.2	21.2	
	µmol/l	78.7	63.0	94.4	Polarisation Fluoroimmunoassay
	µg/ml	18.6	14.9	22.3	
	µmol/l	58.3	46.6	70.0	Ortho Vitros Microslide Systems
	µg/ml	13.8	11.0	16.6	
	µmol/l	67.2	53.8	80.6	Chemiluminescence
	µg/ml	15.9	12.7	19.1	
	µmol/l	66.1	52.9	79.3	Turbidimetric
	µg/ml	15.6	12.5	18.7	
	µmol/l	72.4	57.9	86.9	KIMS
	µg/ml	17.1	13.7	20.5	
Cyclosporin	nmol/l	483	386	580	Enzyme Immunoassay
	ng/ml	581	464	698	
	nmol/l	508	406	610	Chemiluminescence
	ng/ml	611	488	734	
Digoxin	nmol/l	3.50	2.80	4.20	Vitros
	ng/ml	2.73	2.19	3.27	
	nmol/l	3.54	2.83	4.25	Chemiluminescence
	ng/ml	2.76	2.21	3.31	
	nmol/l	3.87	3.10	4.64	Enzyme Immunoassay
	ng/ml	3.02	2.42	3.62	
	nmol/l	3.84	3.07	4.61	KIMS
	ng/ml	3.00	2.40	3.60	
	nmol/l	3.60	2.88	4.32	Turbidimetric
	ng/ml	2.81	2.25	3.37	
Gentamicin	µmol/l	17.1	13.7	20.5	Enzyme Immunoassay
	µg/ml	8.17	6.55	9.79	
	µmol/l	15.2	12.2	18.2	Polarisation Fluoroimmunoassay
	µg/ml	7.27	5.83	8.71	
	µmol/l	17.9	14.3	21.5	Chemiluminescence
	µg/ml	8.56	6.84	10.3	
	µmol/l	20.1	16.1	24.1	Turbidimetric
	µg/ml	9.61	7.70	11.5	

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DRUG CONTROL LEVEL 3 (TDM CONTROL 3)

Cat. No. HD1669 Lot. No. 822DC Size 12 x 5ml Expiry 2023-01-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Gentamicin	µmol/l	12.8	10.2	15.4	KIMS
	µg/ml	6.12	4.88	7.36	
Lithium	mmol/l	1.69	1.49	1.89	Ion selective electrode
	mg/dl	1.17	1.03	1.31	
	mmol/l	1.70	1.50	1.90	Spectrophotometric
	mg/dl	1.18	1.04	1.32	
Methotrexate	µmol/l	9.36	7.49	11.2	Enzyme Immunoassay
	µg/ml	4.25	3.40	5.10	
	µmol/l	8.47	6.78	10.2	Polarisation Fluoroimmunoassay
	µg/ml	3.85	3.08	4.62	
	µmol/l	8.61	6.89	10.3	Chemiluminescence
	µg/ml	3.91	3.13	4.69	
Paracetamol	mmol/l	1.27	1.02	1.52	Colorimetric
	mg/l	192	154	230	
	mmol/l	1.28	1.02	1.54	Enzymatic
	mg/l	194	154	234	
	mmol/l	1.54	1.23	1.85	Turbidimetric
	mg/l	233	186	280	
Phenobarbital	µmol/l	225	180	270	Enzyme Immunoassay
	µg/ml	52.2	41.8	62.6	
	µmol/l	220	176	264	Polarisation Fluoroimmunoassay
	µg/ml	51.0	40.8	61.2	
	µmol/l	222	178	266	Turbidimetric
	µg/ml	51.5	41.3	61.7	
	µmol/l	230	184	276	Chemiluminescence
	µg/ml	53.4	42.7	64.1	
	µmol/l	219	175	263	KIMS
	µg/ml	50.8	40.6	61.0	
Phenytoin	µmol/l	90.6	72.5	109	Vitros
	µg/ml	22.9	18.3	27.5	
	µmol/l	92.4	73.9	111	Enzyme Immunoassay
	µg/ml	23.3	18.7	27.9	
	µmol/l	87.4	69.9	105	Polarisation Fluoroimmunoassay
	µg/ml	22.1	17.6	26.6	
	µmol/l	90.8	72.6	109	Turbidimetric
	µg/ml	22.9	18.3	27.5	
	µmol/l	89.2	71.4	107	Chemiluminescence
	µg/ml	22.5	18.0	27.0	
	µmol/l	89.9	71.9	108	KIMS
	µg/ml	22.7	18.2	27.2	
Salicylic Acid	mmol/l	3.00	2.40	3.60	Colorimetric Trinder
	mg/dl	41.4	33.1	49.7	
	mmol/l	2.98	2.38	3.58	Enzymatic
	mg/dl	41.2	32.9	49.5	
	mmol/l	3.08	2.46	3.70	Spectrophotometric
	mg/dl	42.5	34.0	51.0	

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DRUG CONTROL LEVEL 3 (TDM CONTROL 3)

Cat. No. HD1669 Lot. No. 822DC Size 12 x 5ml Expiry 2023-01-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Theophylline	µmol/l	155	124	186	Chemiluminescence
	µg/ml	27.9	22.3	33.5	
	µmol/l	168	134	202	Enzyme Immunoassay
	µg/ml	30.3	24.1	36.5	
	µmol/l	166	133	199	Polarisation Fluoroimmunoassay
	µg/ml	29.9	24.0	35.8	
	µmol/l	168	134	202	Turbidimetric
	µg/ml	30.3	24.1	36.5	
	µmol/l	164	131	197	KIMS
	µg/ml	29.6	23.6	35.6	
Tobramycin	µmol/l	18.0	14.4	21.6	Enzyme Immunoassay
	µg/ml	8.42	6.74	10.1	
	µmol/l	18.4	14.7	22.1	Turbidimetric
	µg/ml	8.61	6.88	10.3	
Valproic Acid	µmol/l	982	786	1178	Enzyme Immunoassay
	µg/ml	142	113	171	
	µmol/l	962	770	1154	Polarisation Fluoroimmunoassay
	µg/ml	139	111	167	
	µmol/l	977	782	1172	Chemiluminescence
	µg/ml	141	113	169	
	µmol/l	954	763	1145	Turbidimetric
	µg/ml	138	110	166	
Vancomycin	µmol/l	17.9	14.3	21.5	Enzyme Immunoassay
	µg/ml	26.6	21.2	32.0	
	µmol/l	22.0	17.6	26.4	Polarisation Fluoroimmunoassay
	µg/ml	32.7	26.1	39.3	
	µmol/l	19.5	15.6	23.4	Chemiluminescence
	µg/ml	29.0	23.2	34.8	
	µmol/l	18.8	15.0	22.6	Turbidimetric
	µg/ml	27.9	22.3	33.5	

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