

PRODUCT INFORMATION

HD1668

821DC

Please note that while Caffeine, Ethosuximide and Primidone are present in 821DC – Drug Control Level 2, targets and ranges are not provided for these analytes.

CCS6459

DRUG CONTROL (TDM CONTROL 2)

CAT NO. HD1668 **LOT. NO.** 821DC
SIZE: 20 x 5ml **EXPIRY:** 2023-01-28
GTIN: 05055273203585

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.

1. 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.
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 2 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) 028 94451070 or email Technical.Services@randox.com

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DRUG CONTROL LEVEL 2 (TDM CONTROL 2)

Cat. No. HD1668 Lot. No. 821DC Size 12 x 5ml Expiry 2023-01-28

Range					
Analyte	unit	Target	low	high	methods
Amikacin	µmol/l	24.1	19.3	28.9	Enzyme Immunoassay
	µg/ml	14.1	11.3	16.9	
	µmol/l	25.0	20.0	30.0	Polarisation Fluoroimmunoassay
	µg/ml	14.6	11.7	17.5	
	µmol/l	25.4	20.3	30.5	KIMS
	µg/ml	14.9	11.9	17.9	
Carbamazepine	µmol/l	26.2	21.0	31.4	Turbidimetric
	µg/ml	15.3	12.3	18.3	
	µmol/l	42.1	33.7	50.5	Enzyme Immunoassay
	µg/ml	9.95	7.97	11.9	
	µmol/l	40.2	32.2	48.2	Polarisation Fluoroimmunoassay
	µg/ml	9.50	7.61	11.4	
Cyclosporin	µmol/l	36.5	29.2	43.8	Chemiluminescence
	µg/ml	8.63	6.90	10.4	
	µmol/l	35.8	28.6	43.0	Turbidimetric
	µg/ml	8.46	6.76	10.2	
	µmol/l	38.8	31.0	46.6	KIMS
	µg/ml	9.17	7.33	11.0	
Digoxin	nmol/l	219	175	263	Enzyme Immunoassay
	ng/ml	263	210	316	
	nmol/l	218	174	262	Chemiluminescence
	ng/ml	262	209	315	
Gentamicin	nmol/l	1.75	1.40	2.10	Chemiluminescence
	ng/ml	1.37	1.09	1.65	
	nmol/l	1.91	1.53	2.29	Enzyme Immunoassay
	ng/ml	1.49	1.19	1.79	
	nmol/l	1.95	1.56	2.34	KIMS
	ng/ml	1.52	1.22	1.82	
	nmol/l	1.84	1.47	2.21	Turbidimetric
	ng/ml	1.44	1.15	1.73	
Lithium	µmol/l	11.5	9.20	13.8	Enzyme Immunoassay
	µg/ml	5.50	4.40	6.60	
	µmol/l	10.6	8.48	12.7	Polarisation Fluoroimmunoassay
	µg/ml	5.07	4.05	6.09	
	µmol/l	12.2	9.76	14.6	Chemiluminescence
	µg/ml	5.83	4.67	6.99	
	µmol/l	13.2	10.6	15.8	Turbidimetric
	µg/ml	6.31	5.07	7.55	
Lithium	µmol/l	9.19	7.35	11.0	KIMS
	µg/ml	4.39	3.51	5.27	
Lithium	mmol/l	1.13	0.994	1.27	Ion selective electrode
	mg/dl	0.785	0.690	0.880	

DRUG CONTROL LEVEL 2 (TDM CONTROL 2)

Cat. No. HD1668 Lot. No. 821DC Size 12 x 5ml Expiry 2023-01-28

Range					
Analyte	unit	Target	low	high	methods
Lithium	mmol/l	1.17	1.03	1.31	Spectrophotometric
	mg/dl	0.812	0.715	0.909	
Methotrexate	µmol/l	1.21	0.968	1.45	Enzyme Immunoassay
	µg/ml	0.550	0.440	0.660	
	µmol/l	1.22	0.976	1.46	Chemiluminescence
	µg/ml	0.554	0.443	0.665	
Paracetamol	mmol/l	0.501	0.401	0.601	Colorimetric
	mg/l	75.8	60.7	90.9	
	mmol/l	0.516	0.413	0.619	Enzymatic
	mg/l	78.1	62.5	93.7	
	mmol/l	0.603	0.482	0.724	Turbidimetric
	mg/l	91.2	72.9	110	
Phenobarbital	µmol/l	124	99.0	149	Enzyme Immunoassay
	µg/ml	28.8	23.0	34.6	
	µmol/l	121	96.8	145	Polarisation Fluoroimmunoassay
	µg/ml	28.1	22.5	33.7	
	µmol/l	125	100	150	Turbidimetric
	µg/ml	29.0	23.2	34.8	
	µmol/l	131	105	157	Chemiluminescence
	µg/ml	30.4	24.4	36.4	
	µmol/l	127	102	152	KIMS
	µg/ml	29.5	23.7	35.3	
Phenytoin	µmol/l	67.8	54.2	81.4	Enzyme Immunoassay
	µg/ml	17.1	13.7	20.5	
	µmol/l	65.1	52.1	78.1	Polarisation Fluoroimmunoassay
	µg/ml	16.4	13.2	19.6	
	µmol/l	68.4	54.7	82.1	Turbidimetric
	µg/ml	17.3	13.8	20.8	
	µmol/l	67.4	53.9	80.9	Chemiluminescence
	µg/ml	17.0	13.6	20.4	
µmol/l	65.8	52.6	79.0	KIMS	
µg/ml	16.6	13.3	19.9		
Salicylic Acid	mmol/l	1.29	1.03	1.55	Colorimetric Trinder
	mg/dl	17.8	14.2	21.4	
	mmol/l	1.21	0.968	1.45	Enzymatic
	mg/dl	16.7	13.4	20.0	
	mmol/l	1.26	1.01	1.51	Spectrophotometric
	mg/dl	17.4	14.0	20.8	
Theophylline	µmol/l	85.5	68.4	103	Chemiluminescence
	µg/ml	15.4	12.3	18.5	
	µmol/l	89.2	71.4	107	Enzyme Immunoassay
	µg/ml	16.1	12.9	19.3	
	µmol/l	90.8	72.6	109	Polarisation Fluoroimmunoassay
	µg/ml	16.4	13.1	19.7	
	µmol/l	88.2	70.6	106	Turbidimetric
	µg/ml	15.9	12.7	19.1	

DRUG CONTROL LEVEL 2 (TDM CONTROL 2)

Cat. No. HD1668 Lot. No. 821DC Size 12 x 5ml Expiry 2023-01-28

Range					
Analyte	unit	Target	low	high	methods
Theophylline	µmol/l	88.6	70.9	106	KIMS
	µg/ml	16.0	12.8	19.2	
Tobramycin	µmol/l	10.9	8.72	13.1	Enzyme Immunoassay
	µg/ml	5.10	4.08	6.12	
	µmol/l	10.8	8.64	13.0	Turbidimetric
	µg/ml	5.05	4.04	6.06	
Valproic Acid	µmol/l	578	462	694	Enzyme Immunoassay
	µg/ml	83.4	66.7	100	
	µmol/l	550	440	660	Polarisation Fluoroimmunoassay
	µg/ml	79.4	63.5	95.3	
	µmol/l	550	440	660	Chemiluminescence
	µg/ml	79.4	63.5	95.3	
	µmol/l	565	452	678	Turbidimetric
	µg/ml	81.5	65.2	97.8	
Vancomycin	µmol/l	10.4	8.32	12.5	Enzyme Immunoassay
	µg/ml	15.5	12.4	18.6	
	µmol/l	12.2	9.76	14.6	Polarisation Fluoroimmunoassay
	µg/ml	18.1	14.5	21.7	
	µmol/l	10.7	8.56	12.8	Chemiluminescence
	µg/ml	15.9	12.7	19.1	
	µmol/l	10.4	8.32	12.5	Turbidimetric
	µg/ml	15.5	12.4	18.6	