

PRODUCT INFORMATION

HD1667

820DC

Please note that while Caffeine, Ethosuximide and Primidone are present in 820DC – Drug Control Level 1, targets and ranges are not provided for these analytes.

CCS6459

DRUG CONTROL (TDM CONTROL I)

CAT NO. HD1667 **LOT NO.** 820DC
SIZE: 20 x 5ml **EXPIRY:** 2023-01-28
GTIN: 05055273203578

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 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 94451070 or email Technical.Services@randox.com

DRUG CONTROL LEVEL 1 (TDM CONTROL 1)

Cat. No. HD1667 Lot. No. 820DC Size 12 x 5ml Expiry 2023-01-28

Range					
Analyte	unit	Target	low	high	methods
Amikacin	µmol/l	7.93	6.34	9.52	Enzyme Immunoassay
	µg/ml	4.64	3.71	5.57	
	µmol/l	7.16	5.73	8.59	Polarisation Fluoroimmunoassay
	µg/ml	4.19	3.36	5.02	
	µmol/l	6.71	5.37	8.05	KIMS
	µg/ml	3.93	3.14	4.72	
Carbamazepine	µmol/l	6.68	5.34	8.02	Turbidimetric
	µg/ml	3.91	3.13	4.69	
	µmol/l	15.1	12.1	18.1	Enzyme Immunoassay
		µg/ml	3.57	2.86	
	µmol/l	14.2	11.4	17.0	Polarisation Fluoroimmunoassay
		µg/ml	3.36	2.69	
µmol/l	13.2	10.6	15.8	Chemiluminescence	
	µg/ml	3.12	2.51		3.73
µmol/l	13.1	10.5	15.7	Turbidimetric	
	µg/ml	3.10	2.48		3.72
µmol/l	13.7	11.0	16.4	KIMS	
	µg/ml	3.24	2.60		3.88
Cyclosporin	nmol/l	81.6	65.3	97.9	Enzyme Immunoassay
	ng/ml	98.1	78.5	118	
Digoxin	nmol/l	0.608	0.486	0.730	Chemiluminescence
	ng/ml	0.475	0.380	0.570	
	nmol/l	0.629	0.503	0.755	Enzyme Immunoassay
	ng/ml	0.491	0.393	0.589	
	nmol/l	0.614	0.491	0.737	KIMS
	ng/ml	0.480	0.383	0.577	
nmol/l	0.554	0.443	0.665	Turbidimetric	
ng/ml	0.433	0.346	0.520		
Gentamicin	µmol/l	4.68	3.74	5.62	Enzyme Immunoassay
	µg/ml	2.24	1.79	2.69	
	µmol/l	4.59	3.67	5.51	Polarisation Fluoroimmunoassay
	µg/ml	2.19	1.75	2.63	
	µmol/l	4.84	3.87	5.81	Chemiluminescence
	µg/ml	2.31	1.85	2.77	
µmol/l	5.42	4.34	6.50	Turbidimetric	
µg/ml	2.59	2.07	3.11		
Lithium	µmol/l	3.79	3.03	4.55	KIMS
	µg/ml	1.81	1.45	2.17	
	mmol/l	0.486	0.428	0.544	Ion selective electrode
	mg/dl	0.337	0.297	0.377	
mmol/l	0.484	0.426	0.542	Spectrophotometric	
mg/dl	0.336	0.296	0.376		

DRUG CONTROL LEVEL 1 (TDM CONTROL 1)

Cat. No. HD1667 Lot. No. 820DC Size 12 x 5ml Expiry 2023-01-28

Analyte	unit	Target	Range		methods
			low	high	
Methotrexate	µmol/l	0.407	0.326	0.488	Enzyme Immunoassay
	µg/ml	0.185	0.148	0.222	
	µmol/l	0.349	0.279	0.419	Polarisation Fluoroimmunoassay
	µg/ml	0.159	0.127	0.191	
µmol/l	0.377	0.302	0.452	Chemiluminescence	
µg/ml	0.171	0.137	0.205		
Paracetamol	mmol/l	0.152	0.122	0.182	Colorimetric
	mg/l	23.0	18.5	27.5	
	mmol/l	0.161	0.129	0.193	Enzymatic
	mg/l	24.4	19.5	29.3	
mmol/l	0.199	0.159	0.239	Turbidimetric	
mg/l	30.1	24.1	36.1		
Phenobarbital	µmol/l	35.7	28.6	42.8	Enzyme Immunoassay
	µg/ml	8.28	6.64	9.92	
	µmol/l	35.1	28.1	42.1	Polarisation Fluoroimmunoassay
	µg/ml	8.14	6.52	9.76	
	µmol/l	35.4	28.3	42.5	Turbidimetric
	µg/ml	8.21	6.57	9.85	
µmol/l	36.9	29.5	44.3	Chemiluminescence	
µg/ml	8.56	6.84	10.3		
µmol/l	35.7	28.6	42.8	KIMS	
µg/ml	8.28	6.64	9.92		
Phenytoin	µmol/l	18.3	14.6	22.0	Enzyme Immunoassay
	µg/ml	4.62	3.69	5.55	
	µmol/l	17.8	14.2	21.4	Polarisation Fluoroimmunoassay
	µg/ml	4.49	3.59	5.39	
	µmol/l	18.6	14.9	22.3	Turbidimetric
	µg/ml	4.70	3.76	5.64	
µmol/l	18.6	14.9	22.3	Chemiluminescence	
µg/ml	4.70	3.76	5.64		
µmol/l	18.2	14.6	21.8	KIMS	
µg/ml	4.60	3.69	5.51		
Salicylic Acid	mmol/l	0.306	0.245	0.367	Colorimetric Trinder
	mg/dl	4.23	3.38	5.08	
	mmol/l	0.273	0.218	0.328	Enzymatic
	mg/dl	3.77	3.01	4.53	
mmol/l	0.262	0.210	0.314	Spectrophotometric	
mg/dl	3.62	2.90	4.34		
Theophylline	µmol/l	27.8	22.2	33.4	Chemiluminescence
	µg/ml	5.01	4.00	6.02	
	µmol/l	28.7	23.0	34.4	Enzyme Immunoassay
	µg/ml	5.17	4.14	6.20	
	µmol/l	30.1	24.1	36.1	Polarisation Fluoroimmunoassay
	µg/ml	5.42	4.34	6.50	
µmol/l	27.4	21.9	32.9	Turbidimetric	
µg/ml	4.94	3.95	5.93		

DRUG CONTROL LEVEL 1 (TDM CONTROL 1)

Cat. No. HD1667 Lot. No. 820DC Size 12 x 5ml Expiry 2023-01-28

Range					
Analyte	unit	Target	low	high	methods
Theophylline	µmol/l	28.1	22.5	33.7	KIMS
	µg/ml	5.06	4.05	6.07	
Tobramycin	µmol/l	4.56	3.65	5.47	Enzyme Immunoassay
	µg/ml	2.13	1.71	2.55	
	µmol/l	4.85	3.88	5.82	Turbidimetric
	µg/ml	2.27	1.82	2.72	
Valproic Acid	µmol/l	215	172	258	Enzyme Immunoassay
	µg/ml	31.0	24.8	37.2	
	µmol/l	201	161	241	Polarisation Fluoroimmunoassay
	µg/ml	29.0	23.2	34.8	
	µmol/l	204	163	245	Chemiluminescence
	µg/ml	29.4	23.5	35.3	
	µmol/l	208	166	250	Turbidimetric
	µg/ml	30.0	24.0	36.0	
Vancomycin	µmol/l	3.33	2.66	4.00	Enzyme Immunoassay
	µg/ml	4.95	3.95	5.95	
	µmol/l	4.37	3.50	5.24	Polarisation Fluoroimmunoassay
	µg/ml	6.49	5.20	7.78	
	µmol/l	3.25	2.60	3.90	Chemiluminescence
	µg/ml	4.83	3.86	5.80	
	µmol/l	3.33	2.66	4.00	Turbidimetric
	µg/ml	4.95	3.95	5.95	