

**DRUG CONTROL - Multiparameter, human-based****Catalogue Number:**

KG 1667 Drug Control - Level I  
KG 1668 Drug Control - Level II  
KG 1669 Drug Control - Level III

**INTENDED USE**

For use in the quality control of clinical chemistry assays, particularly drug residue analysis.

**CHARACTERISTICS**

BGT Drug Controls are based on lyophilised human serum. Constituent concentrations are available at 3 levels.

**VALUE ASSIGNMENT**

Each batch of serum is distributed to approximately 150 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  $\pm$  2 S.D.

**PREPARATION**

Serum must only be reconstituted using the following procedure:

1. Open the vial carefully, avoiding any loss of material.
2. Reconstitute by pipetting exactly 5 ml of distilled water at +20 to +25°C into the vial.
3. Replace the rubber stopper and leave to stand for 30 minutes out of bright light before use.
4. Swirl gently several times during the reconstitution period to ensure that the contents are completely dissolved.
5. Prior to use, mix the contents by inverting the vials the formation of foam should be avoided. Ensure that no lyophilised material remains unreconstituted.
6. The serum is then ready for use with either a manual test or with an automated instrument.

**STABILITY AND STORAGE**

Unreconstituted serum is stable up to the expiry date shown on the side of each individual bottle when stored at +2 to +8°C. Once reconstituted the components of the Drug Control Sera are stable for 4 weeks at +2 to +8°C in the absence of bacterial contamination.

**PRECAUTIONS AND WARNINGS**

This serum has been tested for the HIV (Human Immunodeficiency Virus) antibody, ABsAg and HCV and found to be non-reactive. However, as no method can offer complete assurance as to the absence of infectious agents, this material should be handled as though capable of transmitting infectious disease.

This product has been developed for **IN VITRO** diagnostic use only.

## Drug-o-trol Level 1 (TDM CONTROL 1)

Art.-Nr.: KG1667 Ch.-B.: 513DC

Inhalt 20 x 5ml Verw. Bis: 2012-07

### Bereich

Parameter	Einheit	Zielwert	Von	Bis	Methoden	
Amikacin	µmol/l	6.25	5.00	7.50	Enzyme Immunoassay	
	µg/ml	3.66	2.93	4.39		
	µmol/l	6.47	5.18	7.76	Polarisation Fluoroimmunoassay	
	µg/ml	3.79	3.03	4.55		
Caffeine	µmol/l	13.4	10.7	16.1	HPLC (Reverse Phase)	
	µg/ml	2.60	2.08	3.12		
Carbamazepine	µmol/l	13.3	10.6	16.0	Enzyme Immunoassay	
	µg/ml	3.14	2.51	3.77		
	µmol/l	13.0	10.4	15.6	HPLC (Reverse Phase)	
	µg/ml	3.07	2.46	3.68		
	µmol/l	13.3	10.6	16.0	Polarisation Fluoroimmunoassay	
	µg/ml	3.14	2.51	3.77		
	µmol/l	12.8	10.2	15.4	Vitros 250/500/700/950/5.1 FS	
	µg/ml	3.03	2.41	3.65		
	µmol/l	12.5	10.0	15.0	Turbidimetric	
	µg/ml	2.96	2.36	3.56		
Cyclosporine	µmol/l	14.6	11.7	17.5	Roche Integra	
	µg/ml	3.45	2.77	4.13		
	nmol/l	84.5	67.6	101	Polarisation Fluoroimmunoassay	
	ng/ml	102	81.3	123		
Digoxin	nmol/L	0.880	0.704	1.06	Vitros	
	ng/ml	0.687	0.550	0.824		
	nmol/L	0.710	0.568	0.852	Chemiluminescence	
	ng/ml	0.555	0.444	0.666		
	nmol/L	0.740	0.592	0.888	Enzyme Immunoassay	
	ng/ml	0.578	0.462	0.694		
	nmol/L	0.830	0.664	0.996	KIMS	
	ng/ml	0.648	0.519	0.777		
nmol/L	0.790	0.632	0.948	Turbidimetric		
ng/ml	0.617	0.494	0.740			
Ethosuximide	µmol/l	222	178	266	HPLC (Reverse Phase)	
	µg/ml	31.5	25.2	37.8		
	µmol/l	240	192	288	GLC (Underivatised)	
	µg/ml	34.0	27.2	40.8		
Gentamicin	µmol/l	4.84	3.87	5.81	Enzyme Immunoassay	
	µg/ml	2.24	1.79	2.69		
	µmol/l	4.60	3.68	5.52	Polarisation Fluoroimmunoassay	
	µg/ml	2.13	1.70	2.56		
	µmol/l	5.00	4.00	6.00	Turbidimetric	
	µg/ml	2.32	1.85	2.79		
	Lithium	mmol/l	0.540	0.475	0.605	Flame photometry
		mg/dl	0.375	0.330	0.420	

## Drug-o-trol Level (TDM CONTROL 1)

Art.-Nr.: KG1667 Ch.-B.: 513DC Inhalt 20 x 5ml Verw. Bis: 2012-07

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Lithium	mmol/l	0.500	0.440	0.560	Ion selective electrode
	mg/dl	0.347	0.306	0.388	
	mmol/l	0.540	0.475	0.605	Spectrophotometric
	mg/dl	0.375	0.330	0.420	
Lithium (Vitros)	mmol/l	0.820	0.656	0.984	Vitros
	mg/dl	0.569	0.456	0.682	
Methotrexate	µmol/l	0.470	0.376	0.564	Enzyme Immunoassay
	µg/ml	0.214	0.171	0.257	
	µmol/l	0.460	0.368	0.552	Polarisation Fluoroimmunoassay
	µg/ml	0.209	0.167	0.251	
Paracetamol	mmol/l	0.190	0.152	0.228	Vitros
	mg/l	28.7	23.0	34.4	
	mmol/l	0.180	0.144	0.216	Polarisation Fluoroimmunoassay
	mg/l	27.2	21.8	32.6	
	mmol/l	0.180	0.144	0.216	Enzymatic
	mg/l	27.2	21.8	32.6	
	mmol/l	0.170	0.136	0.204	Turbidimetric
	mg/l	25.7	20.6	30.8	
Phenobarbitone	µmol/l	33.3	26.6	40.0	Enzyme Immunoassay
	µg/ml	7.73	6.17	9.29	
	µmol/l	34.8	27.8	41.8	Polarisation Fluoroimmunoassay
	µg/ml	8.07	6.45	9.69	
	µmol/l	34.5	27.6	41.4	HPLC (Reverse Phase)
	µg/ml	8.00	6.40	9.60	
	µmol/l	26.6	21.3	31.9	Vitros
	µg/ml	6.17	4.94	7.40	
Phenytoin	µmol/l	16.1	12.9	19.3	Vitros
	µg/ml	4.07	3.26	4.88	
	µmol/l	19.4	15.5	23.3	Enzyme Immunoassay
	µg/ml	4.90	3.91	5.89	
	µmol/l	18.4	14.7	22.1	HPLC (Reverse Phase)
	µg/ml	4.65	3.71	5.59	
	µmol/l	19.4	15.5	23.3	Polarisation Fluoroimmunoassay
	µg/ml	4.90	3.91	5.89	
Primidone	µmol/l	14.8	11.8	17.8	Polarisation Fluoroimmunoassay
	µg/ml	3.23	2.58	3.88	
	µmol/l	14.4	11.5	17.3	HPLC (Reverse Phase)
	µg/ml	3.14	2.51	3.77	
Salicylic Acid	mmol/l	0.320	0.256	0.384	Vitros
	mg/dl	4.42	3.54	5.30	
	mmol/l	0.240	0.192	0.288	Colorimetric Trinder
	mg/dl	3.31	2.65	3.97	

## Drug-o-trol Level 1 (TDM CONTROL 1)

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### Bereich

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Salicylic Acid	mmol/l	0.270	0.216	0.324	Polarisation Fluoroimmunoassay
	mg/dl	3.73	2.98	4.48	
	mmol/l	0.260	0.208	0.312	Enzymatic
	mg/dl	3.59	2.87	4.31	
Theophylline	µmol/l	20.3	16.2	24.4	Vitros
	µg/ml	3.66	2.92	4.40	
	µmol/l	30.5	24.4	36.6	Enzyme Immunoassay
	µg/ml	5.50	4.40	6.60	
	µmol/l	30.4	24.3	36.5	Polarisation Fluoroimmunoassay
	µg/ml	5.48	4.38	6.58	
Tobramycin	µmol/l	29.5	23.6	35.4	Turbidimetric
	µg/ml	5.32	4.25	6.39	
	µmol/l	4.45	3.56	5.34	Enzyme Immunoassay
	µg/ml	2.08	1.67	2.49	
	µmol/l	4.66	3.73	5.59	Polarisation Fluoroimmunoassay
	µg/ml	2.18	1.75	2.61	
Valproic Acid	µmol/l	4.20	3.36	5.04	Turbidimetric
	µg/ml	1.97	1.57	2.37	
	µmol/l	228	182	274	Enzyme Immunoassay
	µg/ml	32.9	26.3	39.5	
	µmol/l	223	178	268	Polarisation Fluoroimmunoassay
	µg/ml	32.2	25.7	38.7	
Vancomycin	µmol/l	226	181	271	Turbidimetric
	µg/ml	32.6	26.1	39.1	
	µmol/l	3.57	2.86	4.28	Enzyme Immunoassay
	µg/ml	5.30	4.25	6.35	
	µmol/l	3.51	2.81	4.21	Polarisation Fluoroimmunoassay
	µg/ml	5.21	4.17	6.25	
µmol/l	3.37	2.70	4.04	Turbidimetric	
µg/ml	5.01	4.01	6.01		