BGT BioGenTechnologies GmbH
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Drug-o-trol Level 3

CE

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 ± 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.

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Drug-o-trol Level 3 (TDM CONTROL 3)

Art.-Nr.: KG1669 Ch.-B.: 518DC Inhalt 20 x 5ml Verw. Bis: 2012-07

			Bereich		
Parameter	**Einheit**	**Zielwert**	**Von**	**Bis**	**Methoden**
Amikacin	µmol/l	47.3	37.8	56.8	Enzyme Immunoassay
	µg/ml	27.7	22.1	33.3	
	µmol/l	47.0	37.6	56.4	Polarisation Fluoroimmunoassay
	µg/ml	27.5	22.0	33.0	
Caffeine	µmol/l	92.2	73.8	111	HPLC (Reverse Phase)
	µg/ml	17.9	14.3	21.5	
Carbamazepine	µmol/l	71.7	57.4	86.0	Enzyme Immunoassay
	µg/ml	16.9	13.6	20.2	
	µmol/l	64.4	51.5	77.3	HPLC (Reverse Phase)
	µg/ml	15.2	12.2	18.2	
	µmol/l	68.6	54.9	82.3	Polarisation Fluoroimmunoassay
	µg/ml	16.2	13.0	19.4	
	µmol/l	59.4	47.5	71.3	Vitros 250/500/700/950/5.1 FS
	µg/ml	14.0	11.2	16.8	
	µmol/l	66.1	52.9	79.3	Turbidimetric
	µg/ml	15.6	12.5	18.7	
	µmol/l	83.3	66.6	100	Roche Integra
	µg/ml	19.7	15.7	23.7	
	µmol/l	76.9	61.5	92.3	KIMS
	µg/ml	18.2	14.5	21.9	
Cyclosporine	nmol/l	483	386	580	Polarisation Fluoroimmunoassay
	ng/ml	581	464	698	
Digoxin	nmol/L	4.54	3.63	5.45	Vitros
	ng/ml	3.55	2.84	4.26	
	nmol/L	4.72	3.78	5.66	Chemiluminescence
	ng/ml	3.69	2.95	4.43	
	nmol/L	4.67	3.74	5.60	Enzyme Immunoassay
	ng/ml	3.65	2.92	4.38	
	nmol/L	4.39	3.51	5.27	Polarisation Fluoroimmunoassay
	ng/ml	3.43	2.74	4.12	
	nmol/L	4.01	3.21	4.81	Beckman CX/LX/Immage
	ng/ml	3.13	2.51	3.75	
	nmol/L	4.94	3.95	5.93	KIMS
	ng/ml	3.86	3.08	4.64	
	nmol/L	4.81	3.85	5.77	Turbidimetric
	ng/ml	3.76	3.01	4.51	
Ethosuximide	µmol/l	947	758	1136	Enzyme Immunoassay
	µg/ml	134	107	161	
	µmol/l	865	692	1038	HPLC (Reverse Phase)
	µg/ml	123	98.1	148	
Gentamicin	µmol/l	17.2	13.8	20.6	Enzyme Immunoassay
	µg/ml	7.96	6.39	9.53	

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Drug-o-trol Level 3 (TDM CONTROL 3)

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Parameter	**Einheit**	**Zielwert**	**Von**	**Bis**	**Methoden**
Gentamicin	µmol/l	17.0	13.6	20.4	Polarisation Fluoroimmunoassay
	µg/ml	7.87	6.30	9.44	
	µmol/l	17.8	14.2	21.4	Turbidimetric
	µg/ml	8.24	6.57	9.91	
	µmol/l	14.4	11.5	17.3	KIMS
	µg/ml	6.67	5.32	8.02	
Lithium	mmol/l	1.93	1.70	2.16	Flame photometry
	mg/dl	1.34	1.18	1.50	
	mmol/l	1.81	1.59	2.03	Ion selective electrode
	mg/dl	1.26	1.10	1.42	
	mmol/l	1.84	1.62	2.06	Spectrophotometric
	mg/dl	1.28	1.12	1.44	
Lithium (Vitros)	mmol/l	2.38	1.90	2.86	Vitros
	mg/dl	1.65	1.32	1.98	
Methotrexate	µmol/l	8.61	6.89	10.3	Enzyme Immunoassay
	µg/ml	3.91	3.13	4.69	
	µmol/l	9.18	7.34	11.0	Polarisation Fluoroimmunoassay
	µg/ml	4.17	3.34	5.00	
Paracetamol	mmol/l	1.49	1.19	1.79	Vitros
	mg/l	225	180	270	
	mmol/l	1.43	1.14	1.72	Colorimetric
	mg/l	216	172	260	
	mmol/l	1.48	1.18	1.78	Polarisation Fluoroimmunoassay
	mg/l	224	179	269	
	mmol/l	1.39	1.11	1.67	Enzymatic
	mg/l	210	168	252	
	mmol/l	1.49	1.19	1.79	Turbidimetric
	mg/l	225	180	270	
Phenobarbitone	µmol/l	214	171	257	Enzyme Immunoassay
	µg/ml	49.6	39.7	59.5	
	µmol/l	211	169	253	Polarisation Fluoroimmunoassay
	µg/ml	49.0	39.2	58.8	
	µmol/l	191	153	229	HPLC (Reverse Phase)
	µg/ml	44.3	35.5	53.1	
	µmol/l	204	163	245	Vitros
	µg/ml	47.3	37.8	56.8	
	µmol/l	216	173	259	Turbidimetric
	µg/ml	50.1	40.1	60.1	
Phenytoin	µmol/l	86.1	68.9	103	Vitros
	µg/ml	21.7	17.4	26.0	
	µmol/l	90.2	72.2	108	Enzyme Immunoassay
	µg/ml	22.8	18.2	27.4	
	µmol/l	85.3	68.2	102	HPLC (Reverse Phase)
	µg/ml	21.5	17.2	25.8	
	µmol/l	94.3	75.4	113	Polarisation Fluoroimmunoassay
	µg/ml	23.8	19.0	28.6	

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Phenytoin	µmol/l	100	80.0	120	Turbidimetric
	µg/ml	25.3	20.2	30.4	
	µmol/l	93.1	74.5	112	KIMS
	µg/ml	23.5	18.8	28.2	
Primidone	µmol/l	62.1	49.7	74.5	Polarisation Fluoroimmunoassay
	µg/ml	13.6	10.8	16.4	
	µmol/l	56.0	44.8	67.2	HPLC (Reverse Phase)
	µg/ml	12.2	9.78	14.6	
Salicylic Acid	mmol/l	2.84	2.27	3.41	Vitros
	mg/dl	39.2	31.4	47.0	
	mmol/l	2.81	2.25	3.37	Colorimetric Trinder
	mg/dl	38.8	31.1	46.5	
	mmol/l	2.92	2.34	3.50	Polarisation Fluoroimmunoassay
	mg/dl	40.3	32.3	48.3	
	mmol/l	2.81	2.25	3.37	Enzymatic
	mg/dl	38.8	31.1	46.5	
Theophylline	µmol/l	201	161	241	Vitros
	µg/ml	36.2	29.0	43.4	
	µmol/l	176	141	211	Enzyme Immunoassay
	µg/ml	31.7	25.4	38.0	
	µmol/l	179	143	215	Polarisation Fluoroimmunoassay
	µg/ml	32.3	25.8	38.8	
	µmol/l	178	142	214	HPLC (Reverse Phase)
	µg/ml	32.1	25.6	38.6	
	µmol/l	179	143	215	Turbidimetric
	µg/ml	32.3	25.8	38.8	
Tobramycin	µmol/l	19.0	15.2	22.8	Enzyme Immunoassay
	µg/ml	8.89	7.11	10.7	
	µmol/l	18.7	15.0	22.4	Polarisation Fluoroimmunoassay
	µg/ml	8.75	7.02	10.5	
	µmol/l	17.4	13.9	20.9	Turbidimetric
	µg/ml	8.14	6.51	9.77	
Valproic Acid	µmol/l	1009	807	1211	Enzyme Immunoassay
	µg/ml	146	116	176	
	µmol/l	1014	811	1217	Polarisation Fluoroimmunoassay
	µg/ml	146	117	175	
	µmol/l	983	786	1180	Chemiluminescence
	µg/ml	142	113	171	
	µmol/l	1010	808	1212	Turbidimetric
	µg/ml	146	117	175	
Vancomycin	µmol/l	20.5	16.4	24.6	Enzyme Immunoassay
	µg/ml	30.5	24.4	36.6	
	µmol/l	19.6	15.7	23.5	Polarisation Fluoroimmunoassay
	µg/ml	29.1	23.3	34.9	
	µmol/l	19.3	15.4	23.2	Turbidimetric
	µg/ml	28.7	22.9	34.5	

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