BGT BioGenTechnologies GmbH
Von-Langen-Weg 10
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Drug-o-trol Level 2

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 2 (TDM CONTROL 2)

Art.-Nr.: KG1668 Ch.-B.: 515DC Inhalt 20 x 5ml Verw. Bis: 2012-07

			Bereich		
Parameter	**Einheit**	**Zielwert**	**Von**	**Bis**	**Methoden**
Amikacin	µmol/l	24.5	19.6	29.4	Enzyme Immunoassay
	µg/ml	14.3	11.5	17.1	
	µmol/l	24.7	19.8	29.6	Polarisation Fluoroimmunoassay
	µg/ml	14.5	11.6	17.4	
Caffeine	µmol/l	41.7	33.4	50.0	HPLC (Reverse Phase)
	µg/ml	8.09	6.48	9.70	
Carbamazepine	µmol/l	37.4	29.9	44.9	Enzyme Immunoassay
	µg/ml	8.84	7.07	10.6	
	µmol/l	35.3	28.2	42.4	HPLC (Reverse Phase)
	µg/ml	8.34	6.67	10.0	
	µmol/l	38.2	30.6	45.8	Polarisation Fluoroimmunoassay
	µg/ml	9.03	7.23	10.8	
	µmol/l	31.7	25.4	38.0	Vitros 250/500/700/950/5.1 FS
	µg/ml	7.49	6.00	8.98	
	µmol/l	37.2	29.8	44.6	Turbidimetric
	µg/ml	8.79	7.04	10.5	
	µmol/l	43.9	35.1	52.7	Roche Integra
	µg/ml	10.4	8.30	12.5	
	µmol/l	39.8	31.8	47.8	KIMS
	µg/ml	9.41	7.52	11.3	
Cyclosporine	nmol/l	246	197	295	Enzyme Immunoassay
	ng/ml	296	237	355	
	nmol/l	220	176	264	Polarisation Fluoroimmunoassay
	ng/ml	265	212	318	
Digoxin	nmol/L	2.59	2.07	3.11	Vitros
	ng/ml	2.02	1.62	2.42	
	nmol/L	2.23	1.78	2.68	Chemiluminescence
	ng/ml	1.74	1.39	2.09	
	nmol/L	2.30	1.84	2.76	Enzyme Immunoassay
	ng/ml	1.80	1.44	2.16	
	nmol/L	2.04	1.63	2.45	Polarisation Fluoroimmunoassay
	ng/ml	1.59	1.27	1.91	
	nmol/L	1.86	1.49	2.23	Beckman CX/LX/Immage
	ng/ml	1.45	1.16	1.74	
	nmol/L	2.45	1.96	2.94	KIMS
	ng/ml	1.91	1.53	2.29	
	nmol/L	2.40	1.92	2.88	Turbidimetric
	ng/ml	1.87	1.50	2.24	
Ethosuximide	µmol/l	531	425	637	Enzyme Immunoassay
	µg/ml	75.3	60.3	90.3	
Gentamicin	µmol/l	11.7	9.36	14.0	Enzyme Immunoassay
	µg/ml	5.42	4.33	6.51	

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Gentamicin	µmol/l	11.8	9.44	14.2	Polarisation Fluoroimmunoassay
	µg/ml	5.46	4.37	6.55	
	µmol/l	11.6	9.28	13.9	Chemiluminescence
	µg/ml	5.37	4.30	6.44	
	µmol/l	12.3	9.84	14.8	Turbidimetric
	µg/ml	5.69	4.56	6.82	
	µmol/l	9.35	7.48	11.2	KIMS
	µg/ml	4.33	3.46	5.20	
Lithium	mmol/l	1.27	1.12	1.42	Flame photometry
	mg/dl	0.882	0.778	0.986	
	mmol/l	1.24	1.09	1.39	Ion selective electrode
	mg/dl	0.861	0.757	0.965	
	mmol/l	1.26	1.11	1.41	Spectrophotometric
	mg/dl	0.875	0.771	0.979	
Lithium (Vitros)	mmol/l	1.67	1.34	2.00	Vitros
	mg/dl	1.16	0.930	1.39	
Methotrexate	µmol/l	1.57	1.26	1.88	Enzyme Immunoassay
	µg/ml	0.713	0.573	0.853	
	µmol/l	1.52	1.22	1.82	Polarisation Fluoroimmunoassay
	µg/ml	0.691	0.554	0.828	
Paracetamol	mmol/l	0.610	0.488	0.732	Vitros
	mg/l	92.3	73.8	111	
	mmol/l	0.570	0.456	0.684	Colorimetric
	mg/l	86.2	69.0	103	
	mmol/l	0.600	0.480	0.720	Polarisation Fluoroimmunoassay
	mg/l	90.8	72.6	109	
	mmol/l	0.560	0.448	0.672	Enzymatic
	mg/l	84.7	67.8	102	
	mmol/l	0.590	0.472	0.708	Turbidimetric
	mg/l	89.3	71.4	107	
Phenobarbitone	µmol/l	119	95.2	143	Enzyme Immunoassay
	µg/ml	27.6	22.1	33.1	
	µmol/l	121	96.8	145	Polarisation Fluoroimmunoassay
	µg/ml	28.1	22.5	33.7	
	µmol/l	111	88.8	133	HPLC (Reverse Phase)
	µg/ml	25.8	20.6	31.0	
	µmol/l	111	88.8	133	Vitros
	µg/ml	25.8	20.6	31.0	
	µmol/l	122	97.6	146	Turbidimetric
	µg/ml	28.3	22.6	34.0	
Phenytoin	µmol/l	61.1	48.9	73.3	Vitros
	µg/ml	15.4	12.3	18.5	
	µmol/l	68.9	55.1	82.7	Enzyme Immunoassay
	µg/ml	17.4	13.9	20.9	
	µmol/l	58.5	46.8	70.2	HPLC (Reverse Phase)
	µg/ml	14.8	11.8	17.8	

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Phenytoin	µmol/l	67.8	54.2	81.4	Polarisation Fluoroimmunoassay
	µg/ml	17.1	13.7	20.5	
	µmol/l	70.1	56.1	84.1	Turbidimetric
	µg/ml	17.7	14.2	21.2	
	µmol/l	64.6	51.7	77.5	KIMS
	µg/ml	16.3	13.1	19.5	
Primidone	µmol/l	37.0	29.6	44.4	Polarisation Fluoroimmunoassay
	µg/ml	8.08	6.46	9.70	
	µmol/l	33.9	27.1	40.7	HPLC (Reverse Phase)
	µg/ml	7.40	5.92	8.88	
Salicylic Acid	mmol/l	1.28	1.02	1.54	Vitros
	mg/dl	17.7	14.1	21.3	
	mmol/l	1.18	0.944	1.42	Colorimetric Trinder
	mg/dl	16.3	13.0	19.6	
	mmol/l	1.20	0.960	1.44	Polarisation Fluoroimmunoassay
	mg/dl	16.6	13.3	19.9	
	mmol/l	1.18	0.944	1.42	Enzymatic
	mg/dl	16.3	13.0	19.6	
Theophylline	µmol/l	87.2	69.8	105	Vitros
	µg/ml	15.7	12.6	18.8	
	µmol/l	89.6	71.7	108	Enzyme Immunoassay
	µg/ml	16.1	12.9	19.3	
	µmol/l	91.5	73.2	110	Polarisation Fluoroimmunoassay
	µg/ml	16.5	13.2	19.8	
	µmol/l	89.4	71.5	107	HPLC (Reverse Phase)
	µg/ml	16.1	12.9	19.3	
	µmol/l	89.5	71.6	107	Turbidimetric
	µg/ml	16.1	12.9	19.3	
	µmol/l	88.0	70.4	106	KIMS
	µg/ml	15.9	12.7	19.1	
Tobramycin	µmol/l	11.6	9.28	13.9	Enzyme Immunoassay
	µg/ml	5.43	4.34	6.52	
	µmol/l	11.7	9.36	14.0	Polarisation Fluoroimmunoassay
	µg/ml	5.48	4.38	6.58	
	µmol/l	11.0	8.80	13.2	Turbidimetric
	µg/ml	5.15	4.12	6.18	
Valproic Acid	µmol/l	601	481	721	Enzyme Immunoassay
	µg/ml	86.7	69.4	104	
	µmol/l	598	478	718	Polarisation Fluoroimmunoassay
	µg/ml	86.3	69.0	104	
	µmol/l	582	466	698	Chemiluminescence
	µg/ml	84.0	67.2	101	
	µmol/l	588	470	706	Turbidimetric
	µg/ml	84.8	67.8	102	
Vancomycin	µmol/l	11.4	9.12	13.7	Enzyme Immunoassay
	µg/ml	16.9	13.5	20.3	

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Vancomycin	µmol/l	10.9	8.72	13.1	Polarisation Fluoroimmunoassay
	µg/ml	16.2	13.0	19.4	
	µmol/l	10.5	8.40	12.6	Turbidimetric
	µg/ml	15.6	12.5	18.7	

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