

**Art.-Nr.:** KG3417  
**Ch.-B.:** 503DC – 508DC  
**Inhalt:** 6 x 3 ml  
**Verw. bis:** 2011-02

**INTENDED USE:**

For use in the calibration of therapeutic drug assays.

**CHARACTERISTICS:**

BGT Therapeutic Drug Calibrators are based on lyophilized human serum. Constituent concentrations are present at 6 levels.

**VALUE ASSIGNMENT**

Each lot of therapeutic drug calibrators are assayed immunoturbidimetrically by BGT Laboratories Limited with reference to a Master Lot of Therapeutic drug calibrators.

**PREPARATION:**

Serum must only be reconstituted using the following procedure:

1. Open each vial carefully.
2. Reconstitute by pipetting exactly **3ml** of redistilled water into each vial.
3. Replace the rubber stopper and leave to stand for 30 mins.
4. Dissolve contents completely by swirling or rotating.
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.

**STABILITY AND STORAGE:**

Unreconstituted serum is stable up to the expiry date shown on the side of each individual bottle when stored at +2 - +8°C. Once reconstituted the components of the Therapeutic Drug Calibrators are stable for 28 days at +2 - +8°C in the absence of bacterial contamination. Freshly reconstituted calibrators may also be stored at or below -20°C for up to 8 weeks.

**WARNINGS AND PRECAUTIONS:**

For *in vitro* diagnostic use only, do not pipette by mouth, exercise the normal precautions required for handling laboratory reagents.

This material has been tested for the HIV (Human Immunodeficiency Virus) antibody, Hbs Ag and HCV antibody and found to be non-reactive using FDA approved methods. However, as 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 disease.

	<b>LEVEL 1</b>	<b>LEVEL 2</b>	<b>LEVEL 3</b>	<b>LEVEL 4</b>	<b>LEVEL 5</b>	<b>LEVEL 6</b>
<b>LOT. NO.</b>	503DC	504DC	505DC	506DC	507DC	508DC
<b>CARBAMAZEPINE µg/ml</b>	0.0	1.95	4.28	8.01	12.17	20.12
<b>DIGOXIN ng/ml</b>	0.0	0.68	1.68	2.88	3.96	5.54
<b>GENTAMICIN µg/ml</b>	0.0	0.75	1.40	3.23	6.44	12.10
<b>PHENOBARBITAL µg/ml</b>	0.0	5.06	9.80	21.00	41.62	79.36
<b>PHENYTOIN µg/ml</b>	0.0	2.80	4.87	9.71	19.99	39.08
<b>THEOPHYLLINE µg/ml</b>	0.0	2.75	5.40	10.87	20.62	43.46
<b>VALPROIC ACID µg/ml</b>	0.0	16.44	28.47	51.51	94.11	144.56

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