

**Chargen-B.: 029TU**  
**Inhalt: 3 x 2ml****Artikel-Nr: KG5003**  
**Verwendbar bis: 2011-10****INTENDED USE**

This product is intended for in-vitro diagnostic use in the quality control of diagnostic assays on clinical chemistry and immunoassay systems. The Tumour Marker Controls are for the control of accuracy and reproducibility.

**DEVICE DESCRIPTION**

The Tumour Marker Controls are supplied at 2 levels, level 2 and 3. Target values and ranges are supplied for tumour markers as listed in the value tables for both 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 from which this product has been derived 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°C to +8°C). Once reconstituted, Tumour Marker Controls are stable for 14 days when stored tightly capped at +2°C to +8°C in the absence of contamination, with the following exceptions: Total PSA and Free PSA are stable for 7 days. Thyroglobulin and Calcitonin should be assayed immediately following reconstitution. No claim is made for the stability of CA 72-4, Calcitonin, Cyfra 21 and NSE. 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°C to +8°C). Stable to expiration date printed on individual vials.

**PREPARATION FOR USE**

Open the vial carefully, avoiding any loss of the material and reconstitute with 2ml of distilled water. Replace the rubber stopper, close the vial and leave to stand for 30 minutes before use. Ensure that all traces of dry material are dissolved by swirling gently.

**MATERIALS PROVIDED**

Tumour Marker Control Level 3 3 x 2ml

**ASSIGNED VALUES**

Each batch of Tumour Marker Controls is submitted to a number of external laboratories and values are assigned from a consensus of results obtained by these laboratories. With each batch a control range is provided for individual parameters and each parameter method.

## TUMOUR MARKER CONTROL LEVEL 3 (TMR CONTROL 3)

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Bereich

Parameter	Einheit	Zielwert	von	bis	Methoden
Alphafoetoprotein	KIU/l = IU/ml	79.1	63.3	94.9	Abbott AXSYM
	ng/ml	95.7	76.6	115	
	KIU/l = IU/ml	86.8	69.4	104	Siemens Advia Centaur
	ng/ml	105	84.0	126	
	KIU/l = IU/ml	80.7	64.6	96.8	Beckman Access
	ng/ml	97.6	78.2	117	
	KIU/l = IU/ml	68.3	54.6	82.0	bioMerieux Vidas
	ng/ml	82.6	66.1	99.0	
	KIU/l = IU/ml	82.9	66.3	99.0	Diasorin Liaison
	ng/ml	100	80.2	120	
	KIU/l = IU/ml	69.0	55.2	82.8	Siemens Immulite 2000
	ng/ml	83.5	66.8	100	
Beta-2-microglobulin	µg/ml = mg/l	3.68	2.94	4.42	Siemens Immulite 2000
CA 15-3	U/ml	68.3	54.6	82.0	bioMerieux Vidas
	U/ml	80.1	64.1	96.1	Diasorin Liaison
	U/ml	81.4	65.1	97.7	Tosoh
	U/ml	130	104	156	Siemens Immulite 2000
	U/ml	67.4	53.9	80.9	Abbott AXSYM
	U/ml	72.9	58.3	87.5	Roche Modular
	U/ml	65.0	52.0	78.0	Roche Elecsys
	U/ml	66.9	53.5	80.3	Beckman Access
	U/ml	85.0	68.0	102	Siemens Advia Centaur
	U/ml	77.4	61.9	92.9	Abbott Architect
CA 19-9	U/ml	52.2	41.8	62.6	bioMerieux Vidas
	U/ml	39.5	31.6	47.4	Tosoh
	U/ml	64.2	51.4	77.0	Diasorin Liaison
	U/ml	54.7	43.8	65.6	Abbott AXSYM
	U/ml	51.9	41.5	62.3	Siemens Immulite 2000
	U/ml	68.1	54.5	81.7	Siemens Advia Centaur
	U/ml	193	154	232	Abbott Architect
	U/ml	46.1	36.9	55.3	Roche Modular
	U/ml	56.3	45.0	67.6	Beckman Access

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CA 19-9	U/ml	45.1	36.1	54.1	Roche Elecsys
CA 72-4	U/ml	14.3	10.7	17.9	Roche Cobas E601
CA125	U/ml	108	86.4	130	bioMerieux Vidas
	U/ml	185	148	222	Tosoh
	U/ml	168	134	202	Diasorin Liaison
	U/ml	119	95.2	143	Siemens Immulite 2000
	U/ml	121	96.8	145	Abbott AXSYM
	U/ml	117	93.6	140	Roche Modular
	U/ml	106	84.8	127	Siemens Advia Centaur
	U/ml	115	92.0	138	Roche Elecsys
Calcitonin	ng/L	907	680	1134	Diasorin Liaison
Carcinoembryonic Antigen (CEA)	ng/ml = µg/l	28.1	22.5	33.7	bioMerieux Vidas
	ng/ml = µg/l	42.6	34.1	51.1	Tosoh
	ng/ml = µg/l	31.0	24.8	37.2	Diasorin Liaison
	ng/ml = µg/l	40.5	32.4	48.6	Siemens Immulite 2000
	ng/ml = µg/l	31.3	25.0	37.6	Abbott AXSYM
	ng/ml = µg/l	28.1	22.5	33.7	Roche Modular
	ng/ml = µg/l	33.3	26.6	40.0	Siemens Advia Centaur
	ng/ml = µg/l	30.3	24.2	36.4	Abbott Architect
	ng/ml = µg/l	32.4	25.9	38.9	Beckman Access
	ng/ml = µg/l	24.2	19.4	29.0	Roche Elecsys
Cyfra 21	ng/ml	393	295	491	Roche Cobas E601
Ferritin	ng/ml = µg/l	336	269	403	bioMerieux Vidas
	ng/ml = µg/l	288	230	346	Tosoh
	ng/ml = µg/l	316	253	379	Siemens Immulite 2000
	ng/ml = µg/l	379	303	455	Abbott AXSYM
	ng/ml = µg/l	374	299	449	Diasorin Liaison
	ng/ml = µg/l	328	262	394	Roche Modular
	ng/ml = µg/l	271	217	325	Beckman Access
	ng/ml = µg/l	363	290	436	Abbott Architect
	ng/ml = µg/l	336	269	403	Siemens Advia Centaur
	ng/ml = µg/l	310	248	372	Immunoturbidimetric
Human Chorionic Gonadotrophin	mU/ml=U/L	42.6	34.1	51.1	Siemens Advia Centaur
Neuron Specific Enolase (NSE)	ng/ml	29.8	22.4	37.3	Diasorin Liaison
PSA Free	ng/ml = µg/l	19.7	14.8	24.6	Diasorin Liaison
	ng/ml = µg/l	65.1	48.8	81.4	bioMerieux Vidas
	ng/ml = µg/l	42.9	32.2	53.6	Tosoh
	ng/ml = µg/l	39.2	29.4	49.0	Abbott AXSYM
	ng/ml = µg/l	42.0	31.5	52.5	Siemens Immulite 2000
	ng/ml = µg/l	43.2	32.4	54.0	Roche Modular
	ng/ml = µg/l	58.8	44.1	73.5	Siemens Advia Centaur
	ng/ml = µg/l	31.8	23.9	39.8	Abbott Architect
	ng/ml = µg/l	39.9	29.9	49.9	Roche Elecsys

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Parameter	Einheit	Zielwert	von	bis	Methoden
PSA Free	ng/ml = µg/l	62.2	46.7	77.8	Beckman Access
PSA Total	ng/ml = µg/l	48.5	36.4	60.6	bioMerieux Vidas
	ng/ml = µg/l	42.0	31.5	52.5	Tosoh
	ng/ml = µg/l	37.8	28.4	47.3	Siemens Immulite 2000
	ng/ml = µg/l	45.1	33.8	56.4	Abbott AXSYM
	ng/ml = µg/l	28.5	21.4	35.6	Diasorin Liaison
	ng/ml = µg/l	62.5	46.9	78.1	Siemens Advia Centaur
	ng/ml = µg/l	56.3	42.2	70.4	Abbott Architect
	ng/ml = µg/l	66.1	49.6	82.6	Roche Modular
	ng/ml = µg/l	61.5	46.1	76.9	Beckman Access
	ng/ml = µg/l	67.0	50.3	83.8	Roche Elecsys
Thyroglobulin	ng/ml	160	120	200	Siemens Immulite 2000