RANDOX 0843 CE

TUMOUR MARKER CONTROL - LEVEL 2 (TMR CONTROL 2)

Cat. No. TU5002 **Lot No.** 123TU
Size: 3 x 2ml **Expiry:** 2017-03

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 2 3 x 2ml

ASSIGNED VALUES
Each batch of Tumour Marker Control 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.

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Size: 3 x 2ml Expiry: 2017-03

			Range		
Analyte	**unit**	**target**	**low**	**high**	**methods**
Alphafoetoprotein	KIU/l = IU/ml	15.1	12.1	18.1	BioMerieux Vidas
	ng/ml	18.3	14.6	22.0	
	KIU/l = IU/ml	14.1	11.3	16.9	Siemens Immulite 2000
	ng/ml	17.1	13.7	20.5	
	KIU/l = IU/ml	18.0	14.4	21.6	Siemens Advia Centaur
	ng/ml	21.8	17.4	26.2	
Beta-2-microglobulin	µg/ml = mg/l	2.33	1.86	2.80	BioMerieux Vidas
	µg/ml = mg/l	1.66	1.33	1.99	Randox Immunoturbidimetric
CA 15-3	U/ml	36.1	28.9	43.3	BioMerieux Vidas
	U/ml	34.8	27.8	41.8	Siemens Immulite 2000
	U/ml	38.1	30.5	45.7	Siemens Advia Centaur
CA 19-9	U/ml	17.6	14.1	21.1	BioMerieux Vidas
	U/ml	15.5	12.4	18.6	Siemens Immulite 2000
	U/ml	21.3	17.0	25.6	Siemens Advia Centaur
CA 72-4	U/ml	9.30	6.98	11.6	Roche Cobas E411
CA125	U/ml	49.6	39.7	59.5	BioMerieux Vidas
	U/ml	38.4	30.7	46.1	Siemens Immulite 2000
	U/ml	52.9	42.3	63.5	Siemens Advia Centaur
Calcitonin	pmol/l	19.3	14.5	24.1	Siemens Immulite 2000
	pg/ml	65.7	49.4	82.0	
Carcinoembryonic Antigen (CEA)	ng/ml = µg/l	4.57	3.66	5.48	BioMerieux Vidas
	ng/ml = µg/l	6.23	4.98	7.48	Siemens Immulite 2000
	ng/ml = µg/l	4.82	3.86	5.78	Siemens Advia Centaur
Cyfra 21-1	ng/ml	5.96	4.47	7.45	Roche Cobas E411
Ferritin	ng/ml = µg/l	35.0	28.0	42.0	BioMerieux Vidas
	ng/ml = µg/l	42.7	34.2	51.2	Randox Immunoturbidimetric
	ng/ml = µg/l	44.2	35.4	53.0	Siemens Immulite 2000
	ng/ml = µg/l	40.3	32.2	48.4	Siemens Advia Centaur
Neuron Specific Enolase (NSE)	ng/ml	2.60	1.95	3.25	Roche Cobas E411
PSA Free	ng/ml = µg/l	3.48	2.61	4.35	BioMerieux Vidas
	ng/ml = µg/l	2.40	1.80	3.00	Siemens Immulite 2000
	ng/ml = µg/l	2.92	2.19	3.65	Siemens Advia Centaur
PSA Total	ng/ml = µg/l	3.67	2.75	4.59	BioMerieux Vidas
	ng/ml = µg/l	3.17	2.38	3.96	Siemens Advia Centaur
Thyroglobulin	ng/ml	7.94	5.96	9.93	Siemens Immulite 2000
Total Beta hCG	mU/ml=IU/l	8.27	6.62	9.92	BioMerieux Vidas
	mU/ml=IU/l	11.4	9.12	13.7	Siemens Immulite 2000
	mU/ml=IU/l	7.84	6.27	9.41	Siemens Advia Centaur