RANDOX 0086 CE

TUMOUR MARKER CONTROL - LEVEL 3 (TMR CONTROL 3)

CAT NO. TU5003
SIZE: 3 x 2 ml
GTIN: 05055273207835
LOT NO. 152TU
EXPIRY: 2018-04

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 2 ml 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 2 ml

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.

11 May '16 ne

RANDOX

TUMOUR MARKER CONTROL - LEVEL 3 (TMR CONTROL 3)

Cat. No. TU5003 Lot No. 152TU

Size: 3 x 2 ml Expiry: 2018-04

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Alphafoetoprotein	KIU/l = IU/ml	86.3	69.0	104	Siemens Centaur XP/XPT/Classic
	ng/ml	104	83.5	125	
	KIU/l = IU/ml	77.5	62.0	93.0	Siemens Immulite 2000
	ng/ml	93.8	75.0	113	
	KIU/l = IU/ml	76.7	61.4	92.0	BioMerieux Vidas
	ng/ml	92.8	74.3	111	
	KIU/l = IU/ml	85.9	68.7	103	Roche Cobas E411
	ng/ml	104	83.1	125	
Beta-2-microglobulin	µg/ml = mg/l	4.18	3.34	5.02	BioMerieux Vidas
	µg/ml = mg/l	4.44	3.55	5.33	Randox Immunoturbidimetric
CA 15-3	U/ml	116	92.8	139	Siemens Centaur XP/XPT/Classic
	U/ml	113	90.4	136	Siemens Immulite 2000
	U/ml	97.9	78.3	117	BioMerieux Vidas
	U/ml	102	81.6	122	Roche Cobas E411
CA 19-9	U/ml	63.2	50.6	75.8	Siemens Centaur XP/XPT/Classic
	U/ml	55.4	44.3	66.5	Siemens Immulite 2000
	U/ml	70.2	56.2	84.2	BioMerieux Vidas
	U/ml	49.3	39.4	59.2	Roche Cobas E411
CA 72-4	U/ml	16.8	12.6	21.0	Roche Cobas E411
CA125	U/ml	199	159	239	Siemens Centaur XP/XPT/Classic
	U/ml	197	158	236	Siemens Immulite 2000
	U/ml	211	169	253	BioMerieux Vidas
	U/ml	198	158	238	Roche Cobas E411
Calcitonin	pmol/l	132	99.0	165	Siemens Immulite 2000
	pg/ml	451	338	564	
Carcinoembryonic Antigen (CEA)	ng/ml = µg/l	49.3	39.4	59.2	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	56.1	44.9	67.3	Siemens Immulite 2000
	ng/ml = µg/l	38.4	30.7	46.1	BioMerieux Vidas
	ng/ml = µg/l	36.4	29.1	43.7	Roche Cobas E411
Cyfra 21-1	ng/ml	36.2	27.2	45.3	Roche Cobas E411
Ferritin	ng/ml = µg/l	271	217	325	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	281	225	337	Siemens Immulite 2000
	ng/ml = µg/l	251	201	301	BioMerieux Vidas
	ng/ml = µg/l	267	214	320	Roche Cobas E411
	ng/ml = µg/l	246	197	295	Randox Immunoturbidimetric
Neuron Specific Enolase (NSE)	ng/ml	34.4	25.8	43.0	Roche Cobas E411
PSA Free	ng/ml = µg/l	26.9	20.2	33.6	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	24.0	18.0	30.0	Siemens Immulite 2000
	ng/ml = µg/l	46.1	34.6	57.6	BioMerieux Vidas
	ng/ml = µg/l	25.9	19.4	32.4	Roche Cobas E411

RANDOX

TUMOUR MARKER CONTROL - LEVEL 3 (TMR CONTROL 3)

Cat. No. TU5003 Lot No. 152TU

Size: 3 x 2 ml Expiry: 2018-04

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
PSA Total	ng/ml = µg/l	37.6	28.2	47.0	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	29.3	22.0	36.6	Siemens Immulite 2000
	ng/ml = µg/l	41.5	31.1	51.9	BioMerieux Vidas
	ng/ml = µg/l	43.5	32.6	54.4	Roche Cobas E411
Thyroglobulin	ng/ml	147	110	184	Siemens Immulite 2000
	ng/ml	165	124	206	Roche Cobas E411
Total Beta hCG	mU/ml=IU/l	82.6	66.1	99.0	Siemens Centaur XP/XPT/Classic
	mU/ml=IU/l	126	101	151	Siemens Immulite 2000
	mU/ml=IU/l	91.7	73.4	110	BioMerieux Vidas
	mU/ml=IU/l	82.1	65.7	98.5	Roche Cobas E411

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com