

TUMOUR MARKER CONTROL - LEVEL 3 (TMR CONTROL 3)

Cat. No. TU5003 **Lot No.** 124TU
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 3 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.

17 Apr '14 ne

TUMOUR MARKER CONTROL - LEVEL 3 (TMR CONTROL 3)

Cat. No. TU5003 Lot No. 124TU

Size: 3 x 2ml Expiry: 2017-03

Range

Analyte	unit	target	low	high	methods
Alphafoetoprotein	KIU/l = IU/ml	81.6	65.3	97.9	BioMerieux Vidas
	ng/ml	98.7	79.0	118	
	KIU/l = IU/ml	80.0	64.0	96.0	Siemens Immulite 2000
	ng/ml	96.8	77.4	116	
Beta-2-microglobulin	KIU/l = IU/ml	90.4	72.3	108	Siemens Advia Centaur
	ng/ml	109	87.5	131	
Beta-2-microglobulin	µg/ml = mg/l	3.79	3.03	4.55	BioMerieux Vidas
	µg/ml = mg/l	3.34	2.67	4.01	Randox Immunoturbidimetric
CA 15-3	U/ml	94.5	75.6	113	BioMerieux Vidas
	U/ml	86.1	68.9	103	Siemens Immulite 2000
	U/ml	99.7	79.8	120	Siemens Advia Centaur
CA 19-9	U/ml	55.8	44.6	67.0	BioMerieux Vidas
	U/ml	41.2	33.0	49.4	Siemens Immulite 2000
	U/ml	52.0	41.6	62.4	Siemens Advia Centaur
CA 72-4	U/ml	27.2	20.4	34.0	Roche Cobas E411
CA125	U/ml	177	142	212	BioMerieux Vidas
	U/ml	124	99.0	149	Siemens Immulite 2000
	U/ml	169	135	203	Siemens Advia Centaur
Calcitonin	pmol/l	90.6	68.0	113	Siemens Immulite 2000
	pg/ml	309	232	386	
Carcinoembryonic Antigen (CEA)	ng/ml = µg/l	28.8	23.0	34.6	BioMerieux Vidas
	ng/ml = µg/l	38.7	31.0	46.4	Siemens Immulite 2000
	ng/ml = µg/l	30.3	24.2	36.4	Siemens Advia Centaur
Cyfra 21-1	ng/ml	36.9	27.7	46.1	Siemens Advia Centaur
Ferritin	ng/ml = µg/l	243	194	292	BioMerieux Vidas
	ng/ml = µg/l	259	207	311	Randox Immunoturbidimetric
	ng/ml = µg/l	280	224	336	Siemens Immulite 2000
	ng/ml = µg/l	303	242	364	Siemens Advia Centaur
Neuron Specific Enolase (NSE)	ng/ml	44.0	33.0	55.0	Siemens Advia Centaur
PSA Free	ng/ml = µg/l	45.0	33.8	56.3	BioMerieux Vidas
	ng/ml = µg/l	32.3	24.2	40.4	Siemens Immulite 2000
	ng/ml = µg/l	39.6	29.7	49.5	Siemens Advia Centaur
PSA Total	ng/ml = µg/l	43.2	32.4	54.0	BioMerieux Vidas
	ng/ml = µg/l	43.4	32.6	54.3	Siemens Immulite 2000
Thyroglobulin	ng/ml	140	105	175	Siemens Immulite 2000
Total Beta hCG	mU/ml=IU/l	83.6	66.9	100	BioMerieux Vidas
	mU/ml=IU/l	112	89.6	134	Siemens Immulite 2000
	mU/ml=IU/l	72.2	57.8	86.6	Siemens Advia Centaur