

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

**CAT NO.** TU5003

**LOT NO.** 333TU

**SIZE:** 3 x 2 ml

**EXPIRY:** 2023-07-28

**GTIN:** 05055273207835

### 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.

EC REP

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

Lot. No. 333TU Cat. No. TU5003

Size 3 x 2 ml Expiry 2023-07-28

Range

Analyte	unit	Target	low	high	methods
Alphafoetoprotein	KIU/l = IU/ml	88.3	70.6	106	BioMerieux Vidas
	ng/ml	107	85.4	129	
	KIU/l = IU/ml	90.9	72.7	109	Siemens Centaur XP/XPT/Classic
	ng/ml	110	88.0	132	
Beta-2-microglobulin	KIU/l = IU/ml	101	80.8	121	Roche Cobas e series
	ng/ml	122	97.8	146	
Beta-2-microglobulin	µg/ml = mg/l	3.94	3.15	4.73	BioMerieux Vidas
	µg/ml = mg/l	4.19	3.35	5.03	Randox Immunoturbidimetric
CA 15-3	U/ml	99.5	79.6	119	BioMerieux Vidas
	U/ml	116	92.8	139	Siemens Centaur XP/XPT/Classic
	U/ml	107	85.6	128	Roche Cobas e series
CA 19-9	U/ml	42.1	33.7	50.5	BioMerieux Vidas
	U/ml	45.1	36.1	54.1	Roche Cobas e series
CA 72-4	U/ml	27.1	20.3	33.9	Roche Cobas e series
CA125	U/ml	139	111	167	BioMerieux Vidas
	U/ml	95.0	76.0	114	Siemens Centaur XP/XPT/Classic
	U/ml	153	122	184	Roche Cobas e series
Calcitonin	pmol/l	98.2	73.7	123	Roche Cobas e series
	pg/ml	335	251	419	
Carcinoembryonic Antigen (CEA)	ng/ml = µg/l	47.4	37.9	56.9	BioMerieux Vidas
	ng/ml = µg/l	46.6	37.3	55.9	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	41.0	32.8	49.2	Roche Cobas e series
Cyfra 21-1	ng/ml	37.4	28.1	46.8	Roche Cobas e series
Ferritin	ng/ml = µg/l	253	202	304	BioMerieux Vidas
	ng/ml = µg/l	221	177	265	Randox Immunoturbidimetric
Neuron Specific Enolase (NSE)	ng/ml	29.7	22.3	37.1	Roche Cobas e series
PSA Free	ng/ml = µg/l >10.0	-	-	-	BioMerieux Vidas
	ng/ml = µg/l >25.0	-	-	-	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	26.3	19.7	32.9	Roche Cobas e series
PSA Total	ng/ml = µg/l	40.0	30.0	50.0	BioMerieux Vidas
	ng/ml = µg/l	31.8	23.9	39.8	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	33.1	24.8	41.4	Roche Cobas e series
Thyroglobulin	ng/ml	164	123	205	Roche Cobas e series
Total Beta hCG	mU/ml=IU/l	167	134	200	BioMerieux Vidas
	IU/ml	0.17	0.13	0.21	
	mU/ml=IU/l	69.3	55.4	83.2	Siemens Centaur XP/XPT/Classic
	IU/ml	0.07	0.06	0.08	
	mU/ml=IU/l	98.1	78.5	118	Roche Cobas e series
IU/ml	0.10	0.08	0.12		