

TUMOUR MARKER CONTROL - LEVEL 2 (TMR CONTROL 2)

CAT. NO. TU5002

LOT NO. 332TU

SIZE: 3 x 2 ml

EXPIRY: 2023-07-28

GTIN: 05055273207828

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 2 3 x 2 ml

ASSIGNED VALUES

Due to the variation caused by test equipment, test reagents and laboratory technique, the quoted ranges are provided for guidance. It is recommended that these ranges are used until each laboratory has established its own ranges, based on individual laboratory requirements.

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
----	-----

Randox Teoranta, Meenmore,
Dungloe, Donegal,
F94 TV06, Ireland

Rev. 11 Nov '21 me

TUMOUR MARKER CONTROL - LEVEL 2 (TMR CONTROL 2)

Lot. No. 332TU Cat. No. TU5002

Size 3 x 2 ml Expiry 2023-07-28

Range

Analyte	unit	Target	low	high	methods
Alphafoetoprotein	KIU/l = IU/ml	17.6	14.1	21.1	BioMerieux Vidas
	ng/ml	21.3	17.1	25.5	
	KIU/l = IU/ml	21.5	17.2	25.8	Siemens Centaur XP/XPT/Classic
	ng/ml	26.0	20.8	31.2	
	KIU/l = IU/ml	21.9	17.5	26.3	Roche Cobas e series
	ng/ml	26.5	21.2	31.8	
Beta-2-microglobulin	µg/ml = mg/l	2.00	1.60	2.40	BioMerieux Vidas
	µg/ml = mg/l	2.05	1.64	2.46	Randox Immunoturbidimetric
CA 15-3	U/ml	39.1	31.3	46.9	BioMerieux Vidas
	U/ml	44.6	35.7	53.5	Siemens Centaur XP/XPT/Classic
	U/ml	43.6	34.9	52.3	Roche Cobas e series
CA 19-9	U/ml	13.4	10.7	16.1	BioMerieux Vidas
	U/ml	15.0	12.0	18.0	Roche Cobas e series
CA 72-4	U/ml	5.69	4.27	7.11	Roche Cobas e series
CA125	U/ml	40.5	32.4	48.6	BioMerieux Vidas
	U/ml	34.4	27.5	41.3	Siemens Centaur XP/XPT/Classic
	U/ml	50.9	40.7	61.1	Roche Cobas e series
Calcitonin	pmol/l	18.4	13.8	23.0	Roche Cobas e series
	pg/ml	62.8	47.1	78.5	
Carcinoembryonic Antigen (CEA)	ng/ml = µg/l	6.61	5.29	7.93	BioMerieux Vidas
	ng/ml = µg/l	6.76	5.41	8.11	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	6.52	5.22	7.82	Roche Cobas e series
Cyfra 21-1	ng/ml	5.08	3.81	6.35	Roche Cobas e series
Ferritin	ng/ml = µg/l	32.1	25.7	38.5	BioMerieux Vidas
	ng/ml = µg/l	32.0	25.6	38.4	Randox Immunoturbidimetric
Neuron Specific Enolase (NSE)	ng/ml	2.08	1.56	2.60	Roche Cobas e series
PSA Free	ng/ml = µg/l	2.44	1.83	3.05	BioMerieux Vidas
	ng/ml = µg/l	1.75	1.31	2.19	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	1.58	1.19	1.98	Roche Cobas e series
PSA Total	ng/ml = µg/l	2.45	1.84	3.06	BioMerieux Vidas
	ng/ml = µg/l	1.83	1.37	2.29	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	1.95	1.46	2.44	Roche Cobas e series
Thyroglobulin	ng/ml	11.7	8.78	14.6	Roche Cobas e series
Total Beta hCG	mU/ml=IU/l	13.2	10.6	15.8	BioMerieux Vidas
	IU/ml	0.0132	0.0106	0.0158	
	mU/ml=IU/l	8.28	6.62	9.94	Siemens Centaur XP/XPT/Classic
	IU/ml	0.0083	0.0066	0.0099	
	mU/ml=IU/l	8.40	6.72	10.1	Roche Cobas e series
	IU/ml	0.0084	0.0067	0.0101	