

TUMOUR MARKER CONTROL - LEVEL 2 (TMR CONTROL 2)

CAT. NO. TU5002 **LOT NO.** 283TU **SIZE:** 3 x 2 ml **EXPIRY:** 2021-05-28

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.

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 I, 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 ($+2^{\circ}$ C to $+8^{\circ}$ C). Once reconstituted, Tumour Marker Controls are stable for 14 days when stored tightly capped at $+2^{\circ}$ C to $+8^{\circ}$ C in the absence of contamination. 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

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TUMOUR MARKER CONTROL LEVEL 2 (TMR CONTROL 2)					
Lot. No. 2, 'TU Cat. No. TU5002					
Size 3 x 2ml Expiry 2021-05-28 Range					
Analyte	unit	Target	low	high	methods
Alphafoetoprotein	KIU/I = IU/ml	23.4	18.7	28.1	Roche Cobas Systems
	ng/ml	28.3	22.6	34.0	
	KIU/I = IU/ml	19.8	15.9	23.8	Siemens Immulite 2000
	ng/ml	24.0	19.2	28.8	
Beta-2-microglobulin	µg/ml = mg/l	1.53	1.22	1.84	Randox Immunoturbidimetric
CA 15-3	U/ml	44.8	35.8	53.7	Roche Cobas Systems
	U/ml	51.7	41.3	62.0	Siemens Centaur XP/XPT/Classic
	U/ml	52.0	41.6	62.4	Siemens Atellica IM
	U/ml	51.3	41.0	61.5	Siemens Immulite 2000
CA 19-9	U/ml	14.2	11.4	17.0	Roche Cobas Systems
	U/ml	21.7	17.4	26.1	Siemens Centaur XP/XPT/Classic
	U/ml	19.3	15.4	23.2	Siemens Atellica IM
	U/ml	15.6	12.5	18.8	Siemens Immulite 2000
CA 72-4	U/ml	4.08	3.06	5.10	Roche Cobas Systems
CA125	U/ml	49.5	39.6	59.4	Roche Cobas Systems
	U/ml	48.4	38.7	58.1	Siemens Centaur XP/XPT/Classic
	U/ml	55.6	44.5	66.7	Siemens Atellica IM
	U/ml	42.2	33.7	50.6	Siemens Immulite 2000
Calcitonin	pmol/l	16.8	12.6	21.0	Roche Cobas Systems
	pg/ml	57.3	43.0	71.6	
	pmol/l	16.1	12.1	20.2	Siemens Immulite 2000
	pg/ml	55.0	41.3	68.7	
Carcinoembryonic Antigen (CEA)	ng/ml = µg/l	5.87	4.70	7.04	Roche Cobas Systems
	ng/ml = μg/l	6.71	5.37	8.05	Siemens Immulite 2000
Cyfra 21-1	ng/ml	4.51	3.38	5.64	Roche Cobas Systems
Neuron Specific Enolase (NSE)	ng/ml	2.04	1.53	2.55	Roche Cobas Systems
Thyroglobulin	ng/ml	11.0	8.23	13.7	Roche Cobas Systems
	ng/ml	2.05	1.54	2.56	Siemens Immulite 2000
Total Beta hCG	mU/ml=IU/l	8.68	6.94	10.4	Roche Cobas Systems
	IU/ml	0.01	0.01	0.01	
	mU/ml=IU/l	29.3	23.4	35.2	Siemens Immulite 2000
	IU/ml	0.03	0.02	0.04	