

**TUMOUR MARKER CONTROL - LEVEL 3 (TMR CONTROL 3)****CAT NO.** TU5003**LOT NO.** 284TU**SIZE:** 3 x 2 ml**EXPIRY:** 2021-05-28**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.

**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. 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

05 Mar 20 bm



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

Lot. No. 2, 4TU Cat. No. TU5003

Size 3 x 2ml Expiry 2021-05-28

Range

Analyte	unit	Target	low	high	methods
Alphafoetoprotein	KIU/l = IU/ml	112	89.4	134	Roche Cobas Systems
	ng/ml	135	108	162	
	KIU/l = IU/ml	91.0	72.8	109	Siemens Immulite 2000
	ng/ml	110	88.1	132	
Beta-2-microglobulin	µg/ml = mg/l	3.35	2.68	4.02	Randox Immunoturbidimetric
CA 15-3	U/ml	116	92.6	139	Roche Cobas Systems
	U/ml	130	104	156	Siemens Centaur XP/XPT/Classic
	U/ml	134	107	161	Siemens Atellica IM
	U/ml	116	92.9	139	Siemens Immulite 2000
CA 19-9	U/ml	40.0	32.0	48.0	Roche Cobas Systems
	U/ml	71.0	56.8	85.2	Siemens Centaur XP/XPT/Classic
	U/ml	61.7	49.3	74.0	Siemens Atellica IM
	U/ml	50.7	40.5	60.8	Siemens Immulite 2000
CA 72-4	U/ml	18.7	14.0	23.4	Roche Cobas Systems
CA125	U/ml	145	116	173	Roche Cobas Systems
	U/ml	144	115	173	Siemens Centaur XP/XPT/Classic
	U/ml	167	133	200	Siemens Atellica IM
	U/ml	125	100	150	Siemens Immulite 2000
Calcitonin	pmol/l	98.7	74.0	123	Roche Cobas Systems
	pg/ml	336	252	420	
	pmol/l	94.8	71.1	119	Siemens Immulite 2000
	pg/ml	323	242	404	
Carcinoembryonic Antigen (CEA)	ng/ml = µg/l	31.8	25.4	38.1	Roche Cobas Systems
	ng/ml = µg/l	45.3	36.2	54.4	Siemens Immulite 2000
Cyfra 21-1	ng/ml	33.0	24.7	41.2	Roche Cobas Systems
Neuron Specific Enolase (NSE)	ng/ml	35.2	26.4	44.0	Roche Cobas Systems
Thyroglobulin	ng/ml	113	84.8	141	Roche Cobas Systems
	ng/ml	94.9	71.1	119	Siemens Immulite 2000
Total Beta hCG	mU/ml=IU/l	99.0	79.2	119	Roche Cobas Systems
	IU/ml	0.10	0.08	0.12	
	mU/ml=IU/l	334	267	401	Siemens Immulite 2000
	IU/ml	0.33	0.27	0.39	