

TUMOUR MARKER CONTROL - LEVEL 3 (TMR CONTROL 3)

CAT NO. TU5003

LOT NO. 341TU

SIZE: 3 x 2 ml

EXPIRY: 2024-05-28

GTIN: 05055273207835

INTENDED USE

This product is intended for *in vitro* diagnostic use, in 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

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.

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Size 3 x 2ml Expiry 2024-05-28

Range

Analyte	unit	Target	low	high	methods
Alphafoetoprotein	KIU/l = IU/ml	107	85.6	128	Roche Cobas e series
	ng/ml	129	104	154	
	KIU/l = IU/ml	105	84.0	126	BioMerieux Vidas
	ng/ml	127	102	152	
	KIU/l = IU/ml	98.3	78.6	118	Siemens Centaur XP/XPT/Classic
	ng/ml	119	95.1	143	
Beta-2-microglobulin	µg/ml = mg/l	3.67	2.94	4.40	Roche Cobas C Systems
CA 15-3	U/ml	107	85.6	128	Roche Cobas e series
	U/ml	92.9	74.3	111	BioMerieux Vidas
	U/ml	131	105	157	Siemens Centaur XP/XPT/Classic
CA 19-9	U/ml	48.0	38.4	57.6	Roche Cobas e series
	U/ml	49.5	39.6	59.4	BioMerieux Vidas
	U/ml	66.0	52.8	79.2	Siemens Centaur XP/XPT/Classic
CA 72-4	U/ml	18.2	13.7	22.8	Roche Cobas e series
CA125	U/ml	124	99.2	149	BioMerieux Vidas
	U/ml	151	121	181	Roche Cobas e series
	U/ml	86.5	69.2	104	Siemens Centaur XP/XPT/Classic
Calcitonin	pmol/l	102	76.4	127	Roche Cobas e series
	pg/ml	347	261	433	
Carcinoembryonic Antigen (CEA)	ng/ml = µg/l	37.6	30.1	45.1	Roche Cobas e series
	ng/ml = µg/l	49.4	39.5	59.3	BioMerieux Vidas
	ng/ml = µg/l	49.5	39.6	59.4	Siemens Centaur XP/XPT/Classic
Cyfra 21-1	ng/ml	32.2	24.2	40.3	Roche Cobas e series
Ferritin	ng/ml = µg/l	288	230	346	Roche Cobas e series
	ng/ml = µg/l	235	188	282	BioMerieux Vidas
	ng/ml = µg/l	247	198	296	Randox Immunoturbidimetric
	ng/ml = µg/l	205	164	246	Siemens Centaur XP/XPT/Classic
Neuron Specific Enolase (NSE)	ng/ml	29.0	21.8	36.3	Roche Cobas e series
PSA Free	ng/ml = µg/l	14.0	10.5	17.5	Roche Cobas e series
	ng/ml = µg/l	22.7	17.0	28.4	Siemens Centaur XP/XPT/Classic
PSA Total	ng/ml = µg/l	27.0	20.3	33.8	BioMerieux Vidas
	ng/ml = µg/l	34.6	26.0	43.3	Roche Cobas e series
	ng/ml = µg/l	31.4	23.6	39.3	Siemens Centaur XP/XPT/Classic
Thyroglobulin	ng/ml	151	113	189	Roche Cobas e series
Total Beta hCG	mU/ml=IU/l	94.5	75.6	113	Roche Cobas e series
	IU/ml	0.0945	0.0756	0.113	
	mU/ml=IU/l	136	109	163	BioMerieux Vidas
	IU/ml	0.1360	0.109	0.163	
	mU/ml=IU/l	46.6	46.6	70.0	Siemens Centaur XP/XPT/Classic
	IU/ml	0.0583	0.0466	0.0700	