TUMOUR MARKER CONTROL - LEVEL 3 (TMR CONTROL 3)

CAT NO. TU5003 **LOT NO.** 311TU
SIZE: 3 x 2 ml **EXPIRY:** 2022-06-28
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: 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.

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Analyte	unit	Target	Range		methods
			low	high	
Alpha-fetoprotein	KIU/l = IU/ml	103	82.4	124	Roche Cobas Systems
	ng/ml	125	100	150	
CA 15-3	U/ml	113	90.4	136	Roche Cobas Systems
CA 19-9	U/ml	40.4	32.3	48.5	Roche Cobas Systems
CA 72-4	U/ml	21.5	16.1	26.9	Roche Cobas Systems
CA125	U/ml	150	120	180	Roche Cobas Systems
Carcinoembryonic Antigen (CEA)	ng/ml = µg/l	32.9	26.3	39.5	Roche Cobas Systems
Cyfra 21-1	ng/ml	36.3	27.2	45.4	Roche Cobas Systems
Neuron Specific Enolase (NSE)	ng/ml	27.8	20.9	34.7	Roche Cobas Systems
Thyroglobulin	ng/ml	131	98.3	164	Roche Cobas Systems
Total beta hCG	mU/ml = IU/l	97.8	78.2	117	Roche Cobas Systems
	IU/ml	0.098	0.078	0.118	

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