PRODUCT INFORMATION

TU5003

375TU

Please note that in Tumour Markers Control - Level 3, lot 375TU, values with TBD are currently unavailable and will be updated in due course.

For any questions or queries, please contact Technical.support@randox.com

CCS INC384

FORM NO. 8373-GP
REVISION (2)
2 Aug 2019

PRODUCT INFORMATION

Tumour Marker Control Level 3

Catalogue Number TU5003

Lot Number 375TU

Please note the level of CA72-4 in TU5003, 375TU is lower than previous Level 3 Tumour Marker Controls and is similar to a level 2 Tumour Marker Control.
The level of CA72-4 in lot 375TU is approximately 5.5U/ml (Roche Cobas e Series).

Please contact technical.services@randox.com if you require any further information or assistance.

Ref qCCS 262/CCS INC261

TUMOUR MARKER CONTROL - LEVEL 3 (TMR CONTROL 3)

CAT NO. TU5003 **LOT NO.** 375TU
SIZE: 3 x 2 ml **EXPIRY:** 2025-06-28
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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Dungloe, Donegal,
F94 TV06, Ireland

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TUMOUR MARKER CONTROL - LEVEL 3 (TMR CONTROL 3)

Lot. No. 375TU Cat. No. TU5003

Size 3 x 2ml Expiry 2025-06-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Alphafoetoprotein	KIU/l = IU/ml	76.4	61.1	91.7	Roche Cobas e series
	ng/ml	92.4	73.9	111	
	KIU/l = IU/ml	TBD	TBD	TBD	BioMerieux Vidas
	ng/ml	TBD	TBD	TBD	
	KIU/l = IU/ml	TBD	TBD	TBD	Siemens Centaur XP/XPT/Classic
	ng/ml	TBD	TBD	TBD	
Beta-2-microglobulin	µg/ml = mg/l	4.48	3.58	5.38	Roche Cobas C Systems
CA 15-3	U/ml	100	80.0	120	Roche Cobas e series
	U/ml	TBD	TBD	TBD	BioMerieux Vidas
	U/ml	TBD	TBD	TBD	Siemens Centaur XP/XPT/Classic
CA 19-9	U/ml	46.7	37.4	56.0	Roche Cobas e series
	U/ml	TBD	TBD	TBD	BioMerieux Vidas
	U/ml	TBD	TBD	TBD	Siemens Centaur XP/XPT/Classic
CA 72-4	U/ml	5.45	4.09	6.81	Roche Cobas e series
CA125	U/ml	TBD	TBD	TBD	BioMerieux Vidas
	U/ml	128	102	154	Roche Cobas e series
	U/ml	TBD	TBD	TBD	Siemens Centaur XP/XPT/Classic
Calcitonin	pmol/l	99.4	74.6	124	Roche Cobas e series
	pg/ml	339	254	424	
Carcinoembryonic Antigen (CEA)	ng/ml = µg/l	29.3	23.4	35.2	Roche Cobas e series
	ng/ml = µg/l	TBD	TBD	TBD	BioMerieux Vidas
	ng/ml = µg/l	TBD	TBD	TBD	Siemens Centaur XP/XPT/Classic
Cyfra 21-1	ng/ml	30.4	22.8	38.0	Roche Cobas e series
Ferritin	ng/ml = µg/l	263	210	316	Roche Cobas e series
	ng/ml = µg/l	TBD	TBD	TBD	BioMerieux Vidas
	ng/ml = µg/l	TBD	TBD	TBD	Randox Immunoturbidimetric
	ng/ml = µg/l	TBD	TBD	TBD	Siemens Centaur XP/XPT/Classic
Neuron Specific Enolase (NSE)	ng/ml	TBD	TBD	TBD	Roche Cobas e series
PSA Free	ng/ml = µg/l	26.4	19.8	33.0	Roche Cobas e series
	ng/ml = µg/l	TBD	TBD	TBD	Siemens Centaur XP/XPT/Classic
PSA Total	ng/ml = µg/l	TBD	TBD	TBD	BioMerieux Vidas
	ng/ml = µg/l	35.5	26.6	44.4	Roche Cobas e series
	ng/ml = µg/l	TBD	TBD	TBD	Siemens Centaur XP/XPT/Classic
Thyroglobulin	ng/ml	135	101	169	Roche Cobas e series
Total Beta hCG	mU/ml=IU/l	92.9	74.3	111	Roche Cobas e series
	IU/ml	0.929	0.0743	0.111	
	mU/ml=IU/l	TBD	TBD	TBD	BioMerieux Vidas
	IU/ml	TBD	TBD	TBD	
	mU/ml=IU/l	TBD	TBD	TBD	Siemens Centaur XP/XPT/Classic
	IU/ml	TBD	TBD	TBD	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com