



# INTERNAL QUALITY CONTROL REPORT

Code:  
L58IC1028, L58IC1029,  
L58IC1030



## Tumor Marker Controls (Level 1 / Level 2 / Level 3)

**Cat No. L58IC1028, L58IC1029, L58IC1030**

**Pack Size: 1x1ml each**

**Intended Use:** The Tumor Marker Controls Level 1, 2, 3 are intended to be used as a quality control material for Tumor Marker assays. They can be used for monitoring Accuracy and Precision.

**Preparation of the Material:** The QC material is supplied in a liquid stable format. Gently swirl the material and it is ready to use.

**Storage & Stability:** Store material at 2-8oC. Unopened QC material is stable up to expiry date when stored at 2-8oC. Once opened the material is stable for a period of 30 days, when stored tightly capped and taking care not to contaminate the material.

**Value Assignment:** Assignment of values is performed using reference laboratories.

**Use:** Use the material as you would use human samples for assays mentioned in this IFU.

### List of Values

**Lot Number:**

**Level 1: TM120180210 Expiry: 2020/02**

**Level 2: TM220180210 Expiry: 2020/02**

**Level 3: TM320180210 Expiry: 2020/02**

Parameter	Level 1	Level 2	Level 3
<b>Alpha-Fetoprotein (AFP) ng/ml</b>			
Beckman Coulter Access	13.5 (10.8 – 16.2)	157 (126 – 188)	305 (244 – 36)
Roche Cobas e411	8.76 (7.01 – 10.5)	110 (88 – 132)	211 (169 – 253)
Siemens Advia Centaur	11.2 (8.96 – 13.4)	137 (110 – 154)	263 (210 – 316)
<b>CA 15-3 U/ml</b>			
Beckman Coulter Access	17.3 (13.8 – 20.8)	458 (36.6 – 55.0)	76.1 (60.9 – 91.3)
Roche Cobas e411	31.0 (24.8 – 37.2)	85.9 (68.7 – 103)	139 (111 – 167)
Siemens Advia Centaur	32.6 (26.1 – 39.1)	97.4 (77.9 – 117)	147 (118 - 176)
<b>CA 19-9 U/ml</b>			
Beckman Coulter Access	31.5 (25.2 – 37.8)	156 (125 – 187)	285 (28 – 342)
Roche Cobas e411	30.0 (24.0 – 36.0)	114 (91.2 – 137)	201 (161 – 241)
Siemens Advia Centaur	57.5 (46.0 – 69.0)	269 (215 – 323)	464 (271 – 557)
<b>CA 125 U/ml</b>			
Beckman Coulter Access	25.0 (20.0 – 30.0)	74.5 (59.6 – 89.4)	130 (104 – 156)
Roche Cobas e411	30.5 (24.4 – 36.6)	101 (80.8 – 121)	172 (138 – 206)

Siemens Advia Centaur	31.6 (25.3 – 37.9)	99.1 (79.3 – 119)	156 (125 – 187)
Carcinoembryonic Antigen (CEA) ng/ml			
Beckman Coulter Access	3.36 (2.69 – 4.03)	26.8 (21.4 – 32.2)	51.2 (41.0 – 61.4)
Roche Cobas e411	3.63 (2.90 – 4.36)	22.1 (17.7 – 26.5)	39.5 (31.6 – 47.4)
Siemens Advia Centaur	2.89 (2.31 – 3.47)	20.9 (16.7 – 25.1)	37.8 (30.2 – 45.4)
Prostate Specific Antigen (PSA) ng/ml			
Beckman Coulter Access	1.56 (1.25 – 1.87)	15.0 (12.0 – 18.0)	29.0 (23.2 – 34.8)
Roche Cobas e411	1.31 (1.05 – 1.57)	12.0 (9.60 – 14.4)	22.7 (18.2 – 27.2)
Siemens Advia Centaur	1.12 (0.896 – 1.34)	10.9 (8.72 – 13.1)	20.0 (16.0 – 24.0)
Free Prostate Specific Antigen (FPSA) ng/ml			
Beckman Coulter Access	0.33 (0.264 – 0.396)	2.72 (2.18 – 3.26)	5.28 (4.22 – 6.34)
Roche Cobas e411	0.248 (0.198 – 0.298)	2.13 (1.70 – 2.56)	3.98 (3.18 – 4.78)
CA 72-4 U/ml			
Roche Cobas e411	4.70 (3.76 – 5.64)	22.4 (17.9 – 26.9)	42.3 (33.8 – 50.8)
Cyfra 21-1 ng/ml			
Roche Cobas e411	5.20 (4.16 – 6.24)	43.2 (34.6 – 51.8)	82.8 (66.2 – 99.4)

All human materials used in the preparation of this control have been tested by approved methods and found non- reactive for HIV, HCV and HBsAg. Even though these methods are highly accurate, laboratory personnel must handle these controls as if they are potentially infectious.



SC Tody Laboratories INT. SRL

Address: Vadul Moldovei Street, no 22, Sector 1, Bucharest, Romania

Tel.: +4021 269 00 00 Fax: +4021 269 06 41

[www.todylaboratories.com](http://www.todylaboratories.com)