Carcinoembryonic Antigen (CEA) IMR Reagent

REF MF-CEA-0061

For *In Vitro* Diagnostic & Professional Use

Intended Use

Use Carcinoembryonic Antigen (CEA) IMR Reagent only with the XacPro-E System (MagQu Co., Ltd.). The reagent is used to quantitatively measure CEA protein in human fluid specimen, such as serum.

Summary & Explanation

Human carcinoembryonic antigen (CEA) (MW = 175,000 – 200,000 g/mol) is a glycoprotein involved in cell adhesion. It is normally produced during fetal development, but the production of CEA stops before birth. Therefore, it is not usually present in the blood of healthy adults, although levels are raised in heavy smokers. Both benign and malignant (harmless and cancerous) conditions can increase the CEA level in blood. The most frequent cancer which causes an increased CEA concentration is cancer of the colon and rectum (Colorectal Cancer, CRC). The normal range for CEA concentration in an adult non-smoker is < 2.5 ng/ml and for a smoker < 5.0 ng/ml in blood. [1, 2]

CEA (ng/mL)	ColoRectal Cancer
> 10	High risk
2.5 (5.0) -10	Low risk
< 2.5 (5.0)	Normal (Smoker)

Principles of Test

The Carcinoembryonic Antigen (CEA) IMR Reagent is designed for rapid quantifying CEA by Immuno Magnetic Reduction (IMR). We conjugated the antibody on the surface of around 50 nm-in-diameter Fe_3O_4 magnetic particles. When the antibodies on the surface bind with CEA, the magnetic particles form clusters. Therefore, the ac susceptibility (X_{ac}) of magnetic particles would be reduced in the adding ac magnetic field. By measuring the reduction of X_{ac}, we can quantify CEA protein in the sample easily, rapidly, and accurately.[3,4]

Reagents

Carcinoembryonic Antigen (CEA) IMR reagent ……4 x 1 mL (100 tests)

Storage Conditions & Stability

Storage reagent at 2 ~8 ℃, the shelf life is 12 weeks.

Statement of Warnings

1. Do not be frozen.
2. Please keep away from events with strong magnetism.
3. For *in vitro* diagnostic use only.
4. For professional use only.
5. Do not use the reagent when it has taken out form 2~8 ℃ over 24 hours. Do not use the reagent when it has something precipitated.

Reagent Preparation

Please use the Carcinoembryonic Antigen (CEA) IMR reagents at room temperature (15-30℃).

Specimen Collection & Preparation

1. Collect all blood samples by wearing protective equipment and following universal precautions for venipuncture. Whole blood is collected in an anticoagulant-free serum separation tube (red top).
2. Ensure that complete clot formation has taken place prior to centrifugation.
3. Centrifuge the serum separation tube for 10 minutes at 1,500-2,000 x g to separate the serum from the red blood cells.
4. After centrifugation, serum is taken for measurement immediately or deep frozen (-20°C or colder) until needed. Avoid repeated freezing or thawing.

Procedure

1. Add 60μ L sample to glass testing tube.
2. Add 40μ L magnetic reagent to glass tube, and mix well.
3. Put the glass tube on the measuring site of IMR analyzer.
4. Wait for the end of reaction and read the result.
5. Use the table 1 for converting to the concentration of CEA antigen as reference.

Results

By using XacPro-E, we can get two signals: one is the AC signal before the reaction (Xac_0) and the other is the AC signal after reaction (Xac). Then we can have the IMR (%) through two signal by following function :

$$IMR(\%) = \frac{Xac_0 - Xac}{Xac_0}$$

IMR (%), as functions of CEA antigen concentration ϕ_{CEA} are explored and are found to follow the logistic function:

$$IMR(\%) = \frac{A - B}{1 + (\frac{\phi_{CEA}}{\phi_o})^{\gamma}} + B$$

where A, B, ϕ_o, and γ are fitting parameters. For CEA, A = 1.01, B = 4.25, ϕ_o = 33.35, and γ = 0.76. The concentration of CEA antigen can be available by following equation. And you can find the table for converting to the concentration of CEA as reference.

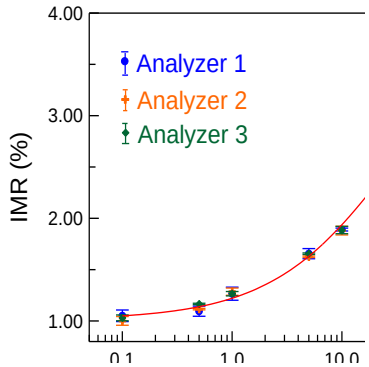

Fig.1 The IMR standard curve of CEA concentration in serum.

Limitations

1. The analytical range of reagent is from 0.13 to 100 ng/mL. When the specimen with CEA protein > 100 ng/mL is to be determined, carry out the following procedures to obtain the accurate concentration. Dilute the specimen, re-assay, and multiply the assayed CEA protein value by the dilution factor.
2. Reagents should be used before the expiration date printed on the kit label.
3. Data is based upon human serum sample.

References

1. Perkins GL, Slater ED, Sanders GK, *et al*; Serum tumor markers. Am Fam Physician. 2003 Sep 15;68(6):1075-82.
2. Duffy MJ; Carcinoembryonic antigen as a marker for colorectal cancer: is it clinically useful? Clin Chem. 2001 Apr;47(4):624-30.
3. Hong, C.Y., Wu, C.C., Chiu, Y.C., Yang, S.Y., Horng, H.E., Yang, H.C., 2006. *Appl. Phys. Lett. 88*, 212512-1 – 212512-3.
4. Che-Chuan Yang, Shieh-Yueh Yang, Chia-Shin Ho, *et al*."Development of antibody functionalized magnetic nanoparticles for the immunoassay of carcinoembryonic antigen: a feasibility study for clinical use." Journal of Nanobiotechnology 2014, 12:44.

Table 1. IMR(%) vs [CEA]

IMR(%)	[CEA] ng/ml	IMR(%)	[CEA] ng/ml	IMR(%)	[CEA] ng/ml	IMR(%)	[CEA] ng/ml
1.05	<0.13	1.61	4.75	2.17	15.47	2.73	39.24
1.06	0.14	1.62	4.88	2.18	15.74	2.74	39.89
1.07	0.18	1.63	5.01	2.19	16.02	2.75	40.54
1.08	0.22	1.64	5.14	2.20	16.30	2.76	41.21
1.09	0.26	1.65	5.27	2.21	16.59	2.77	41.89
1.10	0.31	1.66	5.41	2.22	16.88	2.78	42.58
1.11	0.36	1.67	5.55	2.23	17.18	2.79	43.29
1.12	0.41	1.68	5.69	2.24	17.48	2.80	44.00
1.13	0.46	1.69	5.83	2.25	17.78	2.81	44.73
1.14	0.51	1.70	5.97	2.26	18.09	2.82	45.47
1.15	0.57	1.71	6.12	2.27	18.40	2.83	46.23
1.16	0.62	1.72	6.27	2.28	18.72	2.84	47.00
1.17	0.68	1.73	6.42	2.29	19.04	2.85	47.78
1.18	0.74	1.74	6.57	2.30	19.36	2.86	48.58
1.19	0.80	1.75	6.72	2.31	19.69	2.87	49.39
1.20	0.86	1.76	6.88	2.32	20.03	2.88	50.22
1.21	0.93	1.77	7.03	2.33	20.37	2.89	51.06
1.22	0.99	1.78	7.20	2.34	20.71	2.90	51.92
1.23	1.06	1.79	7.36	2.35	21.06	2.91	52.80
1.24	1.13	1.80	7.52	2.36	21.42	2.92	53.69
1.25	1.20	1.81	7.69	2.37	21.78	2.93	54.60
1.26	1.27	1.82	7.86	2.38	22.15	2.94	55.53
1.27	1.35	1.83	8.03	2.39	22.52	2.95	56.48
1.28	1.42	1.84	8.20	2.40	22.89	2.96	57.44
1.29	1.50	1.85	8.38	2.41	23.28	2.97	58.42
1.30	1.58	1.86	8.56	2.42	23.66	2.98	59.42
1.31	1.66	1.87	8.74	2.43	24.06	2.99	60.45
1.32	1.74	1.88	8.92	2.44	24.46	3.00	61.49
1.33	1.82	1.89	9.11	2.45	24.86	3.01	62.56
1.34	1.90	1.90	9.30	2.46	25.28	3.02	63.64
1.35	1.99	1.91	9.49	2.47	25.70	3.03	64.75
1.36	2.07	1.92	9.68	2.48	26.12	3.04	65.88
1.37	2.16	1.93	9.88	2.49	26.55	3.05	67.04
1.38	2.25	1.94	10.07	2.50	26.99	3.06	68.22
1.39	2.34	1.95	10.27	2.51	27.43	3.07	69.42
1.40	2.44	1.96	10.48	2.52	27.89	3.08	70.65
1.41	2.53	1.97	10.69	2.53	28.34	3.09	71.91
1.42	2.63	1.98	10.90	2.54	28.81	3.10	73.19
1.43	2.72	1.99	11.11	2.55	29.28	3.11	74.51
1.44	2.82	2.00	11.32	2.56	29.76	3.12	75.85
1.45	2.92	2.01	11.54	2.57	30.25	3.13	77.22
1.46	3.02	2.02	11.76	2.58	30.75	3.14	78.62
1.47	3.13	2.03	11.99	2.59	31.25	3.15	80.05
1.48	3.23	2.04	12.21	2.60	31.76	3.16	81.52
1.49	3.34	2.05	12.44	2.61	32.28	3.17	83.02
1.50	3.45	2.06	12.68	2.62	32.81	3.18	84.56
1.51	3.56	2.07	12.91	2.63	33.35	3.19	86.13
1.52	3.67	2.08	13.15	2.64	33.90	3.20	87.73
1.53	3.78	2.09	13.40	2.65	34.45	3.21	89.38
1.54	3.90	2.10	13.64	2.66	35.02	3.22	91.07
1.55	4.01	2.11	13.89	2.67	35.59	3.23	92.79
1.56	4.13	2.12	14.15	2.68	36.17	3.24	94.56
1.57	4.25	2.13	14.40	2.69	36.77	3.25	96.37
1.58	4.37	2.14	14.66	2.70	37.37	3.26	98.23
1.59	4.50	2.15	14.93	2.71	37.98	3.27	>100.00
1.60	4.62	2.16	15.20	2.72	38.61		

MagQu Co., Ltd.

3F., No.12, Lane 538, Zhongzheng Rd., Xindian Dist., New Taipei City 231, Taiwan
Tel: +886-2-8667-1897 Fax: +886-2-8667-1809
E-mail: info@magqu.com Website : www.magqu.com

Rev. Sep. 01, 2015

EC REP **MedNet GmbH**
Borkstraße 10 48163 Münster Germany

癌胚抗原蛋白 (CEA) 免疫磁減量檢測試劑

REF MF-CEA-0061

CE Magqu

本產品僅供體外診斷及專業用途

目的

癌胚抗原蛋白(CEA)免疫磁減量檢測試劑需搭配XacPro-E系統 (磁量生技)使用。此試劑用於檢測人類流狀檢體，如血清之癌胚抗原蛋白濃度。

簡介

人類癌胚蛋白(Carcinoembryonic Antigen, CEA) (MW = 175000 – 200000 g/mol)是一種與細胞附著相關的醣蛋白。通常在胎兒發展時會大量生產，但於出生後便停止。因此除了重度吸菸者外，在正常成人血液中不會有癌胚蛋白存在。但是無論良性或惡性腫瘤患者都可以偵測到血液中癌胚蛋白濃度上升。而與癌胚蛋白濃度上升最息息相關的癌症是大腸直腸癌(Colorectal Cancer， CRC)。在成人(為非吸菸者)血液中癌胚蛋白正常濃度是 < 2.5 ng/ml，成人吸菸者則為 < 5.0 ng/ml。[1, 2]

CEA (ng/mL)	罹癌風險度
> 10	高風險
2.5 (5.0) -10	低風險
< 2.5 (5.0)	正常值(吸菸者)

檢測原理

癌胚抗原蛋白(CEA)免疫磁減量檢測試劑是利用免疫磁減量平台來快速定量癌胚蛋白濃度。癌胚蛋白抗體接於直徑約 50 nm 的 Fe_3O_4 磁珠表面。當磁珠表面抗體與癌胚蛋白結合後，磁珠會聚集成較大的分子，磁珠在外加磁場下產生的磁感量會因此減少。透過磁感量的量測，我們可以非常簡單、快速、精確地測得癌胚蛋白濃度。[3,4]

試劑規格

癌胚抗原蛋白(CEA)免疫磁減量檢測試劑 ……4 x 1 mL (100 個反應)

保存條件

請將本試劑保存於 2 ~8 ℃，可保存 12 週。

注意事項

1. 請勿冷凍。
2. 請遠離具有強力磁性物品。
3. 本檢測試劑僅供體外診斷使用。
4. 本檢測試劑僅供專業用途。
5. 如離開保存環境超過 24 小時，請勿繼續使用；當試劑發生沉澱現象， 請勿繼續使用。

試劑的準備

使用前請將本產品回復至室溫狀態(15~30 ℃)。

樣品的收集

1. 請使用抗凝血集血管(紅頭管)採血；採血時請著帶防護配件以及遵守靜脈抽血的標準注意事項。
2. 血液樣品離心前請確認集血管中的血液已完全凝血。
3. 以 1,500-2,000 x g 離心集血管，以分離血清及血球。
4. 將血清以吸管吸取至乾淨離心管，儲存於-20 ℃或更低溫度冷凍保存。待使用時取出解凍；血清樣品避免重複冷凍及解凍。

操作步驟

1. 將 60 µL 檢體加入樣品管。
2. 另取 40 µL 檢測試劑加入樣品管。
3. 混合均勻後，將樣品管置於免疫分析儀樣品量測區。
4. 待反應結束後，讀取結果。
5. 將所得的結果對照表1，轉換為癌胚蛋白(CEA)的濃度。

結果

透過免疫磁性分析儀的量測，我們可以得到反應前的磁性訊號（Xac_0）與反應結束後的磁性訊號(Xac)。藉由反應前後的磁性訊號差異，我們可以得到免疫磁減量(IMR)的結果：

$$IMR(\%) = \frac{Xac_0 - Xac}{Xac_0}$$

免疫磁減量結果再透過 logistic 方程式換算成癌胚蛋白濃度， 方程式如下:

$$IMR(\%) = \frac{A - B}{1 + (\frac{\phi_{CEA}}{\phi_o})^{\gamma}} + B$$

癌胚蛋白標準式中，A = 1.01, B = 4.25, ρ = 0.76及ϕ_o = 33.35。依此方程式，可以將IMR值轉換成CEA濃度值。請參照對照表轉換IMR檢測值為CEA濃度值。

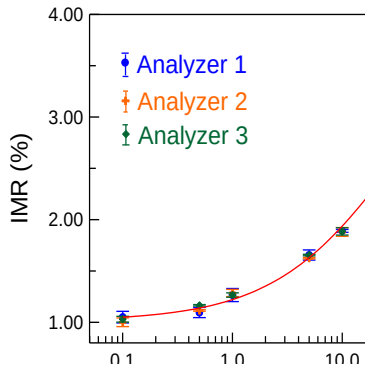

圖.1 癌胚蛋白的免疫磁減量標準曲線

產品限制

1. 本產品適用的濃度分析範圍為 0.13 - 100 ng/mL。當檢測結果大於 100 ng/mL 時，請稀釋檢體至適用範圍並再次檢測。
2. 試劑請在瓶身標示之有效期限內使用方能達到最佳的效果。.
3. 本產品僅適用於人類血清。

參考文獻

1. Perkins GL, Slater ED, Sanders GK, *et al*; Serum tumor markers. Am Fam Physician. 2003 Sep 15;68(6):1075-82.
2. Duffy MJ; Carcinoembryonic antigen as a marker for colorectal cancer: is it clinically useful? Clin Chem. 2001 Apr;47(4):624-30.
3. Hong, C.Y., Wu, C.C., Chiu, Y.C., Yang, S.Y., Horng, H.E., Yang, H.C., 2006. *Appl. Phys. Lett. 88*, 212512-1–212512-3.
4. Che-Chuan Yang, Shieh-Yueh Yang, Chia-Shin Ho, *et al*."Development of antibody functionalized magnetic nanoparticles for the immunoassay of carcinoembryonic antigen: a feasibility study for clinical use." Journal of Nanobiotechnology 2014, 12:44.

表 1. IMR(%) vs [CEA]

IMR(%)	[CEA] ng/ml	IMR(%)	[CEA] ng/ml	IMR(%)	[CEA] ng/ml	IMR(%)	[CEA] ng/ml
1.05	<0.13	1.61	4.75	2.17	15.47	2.73	39.24
1.06	0.14	1.62	4.88	2.18	15.74	2.74	39.89
1.07	0.18	1.63	5.01	2.19	16.02	2.75	40.54
1.08	0.22	1.64	5.14	2.20	16.30	2.76	41.21
1.09	0.26	1.65	5.27	2.21	16.59	2.77	41.89
1.10	0.31	1.66	5.41	2.22	16.88	2.78	42.58
1.11	0.36	1.67	5.55	2.23	17.18	2.79	43.29
1.12	0.41	1.68	5.69	2.24	17.48	2.80	44.00
1.13	0.46	1.69	5.83	2.25	17.78	2.81	44.73
1.14	0.51	1.70	5.97	2.26	18.09	2.82	45.47
1.15	0.57	1.71	6.12	2.27	18.40	2.83	46.23
1.16	0.62	1.72	6.27	2.28	18.72	2.84	47.00
1.17	0.68	1.73	6.42	2.29	19.04	2.85	47.78
1.18	0.74	1.74	6.57	2.30	19.36	2.86	48.58
1.19	0.80	1.75	6.72	2.31	19.69	2.87	49.39
1.20	0.86	1.76	6.88	2.32	20.03	2.88	50.22
1.21	0.93	1.77	7.03	2.33	20.37	2.89	51.06
1.22	0.99	1.78	7.20	2.34	20.71	2.90	51.92
1.23	1.06	1.79	7.36	2.35	21.06	2.91	52.80
1.24	1.13	1.80	7.52	2.36	21.42	2.92	53.69
1.25	1.20	1.81	7.69	2.37	21.78	2.93	54.60
1.26	1.27	1.82	7.86	2.38	22.15	2.94	55.53
1.27	1.35	1.83	8.03	2.39	22.52	2.95	56.48
1.28	1.42	1.84	8.20	2.40	22.89	2.96	57.44
1.29	1.50	1.85	8.38	2.41	23.28	2.97	58.42
1.30	1.58	1.86	8.56	2.42	23.66	2.98	59.42
1.31	1.66	1.87	8.74	2.43	24.06	2.99	60.45
1.32	1.74	1.88	8.92	2.44	24.46	3.00	61.49
1.33	1.82	1.89	9.11	2.45	24.86	3.01	62.56
1.34	1.90	1.90	9.30	2.46	25.28	3.02	63.64
1.35	1.99	1.91	9.49	2.47	25.70	3.03	64.75
1.36	2.07	1.92	9.68	2.48	26.12	3.04	65.88
1.37	2.16	1.93	9.88	2.49	26.55	3.05	67.04
1.38	2.25	1.94	10.07	2.50	26.99	3.06	68.22
1.39	2.34	1.95	10.27	2.51	27.43	3.07	69.42
1.40	2.44	1.96	10.48	2.52	27.89	3.08	70.65
1.41	2.53	1.97	10.69	2.53	28.34	3.09	71.91
1.42	2.63	1.98	10.90	2.54	28.81	3.10	73.19
1.43	2.72	1.99	11.11	2.55	29.28	3.11	74.51
1.44	2.82	2.00	11.32	2.56	29.76	3.12	75.85
1.45	2.92	2.01	11.54	2.57	30.25	3.13	77.22
1.46	3.02	2.02	11.76	2.58	30.75	3.14	78.62
1.47	3.13	2.03	11.99	2.59	31.25	3.15	80.05
1.48	3.23	2.04	12.21	2.60	31.76	3.16	81.52
1.49	3.34	2.05	12.44	2.61	32.28	3.17	83.02
1.50	3.45	2.06	12.68	2.62	32.81	3.18	84.56
1.51	3.56	2.07	12.91	2.63	33.35	3.19	86.13
1.52	3.67	2.08	13.15	2.64	33.90	3.20	87.73
1.53	3.78	2.09	13.40	2.65	34.45	3.21	89.38
1.54	3.90	2.10	13.64	2.66	35.02	3.22	91.07
1.55	4.01	2.11	13.89	2.67	35.59	3.23	92.79
1.56	4.13	2.12	14.15	2.68	36.17	3.24	94.56
1.57	4.25	2.13	14.40	2.69	36.77	3.25	96.37
1.58	4.37	2.14	14.66	2.70	37.37	3.26	98.23
1.59	4.50	2.15	14.93	2.71	37.98	3.27	>100.00
1.60	4.62	2.16	15.20	2.72	38.61		

MagQu Co., Ltd.

231 新北市新店區中正路 538 巷 12 號 3 樓
電話: +886-2-8667-1897　　傳真: +886-2-8667-1809
E-mail: info@magqu.com　　網頁: www.magqu.com

EC REP **MedNet GmbH**
Borkstraße 10 48163 Münster Germany

Rev. Sep. 01, 2015