

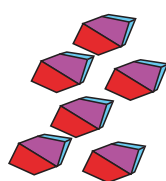


Access
Tumor
Markers

CEA

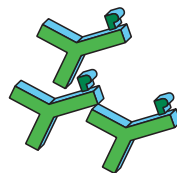
- One step dual monoclonal antibody assay
- Broad dynamic range up to 1000 ng/mL
- No hook effect up to 100,000 ng/mL
- Time to first result: 15 minutes
- Calibration curve stability: 28 days

1 step sandwich technique



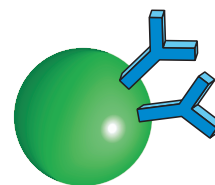
Sample containing CEA

+



Anti-CEA MAb alkaline phosphatase conjugate

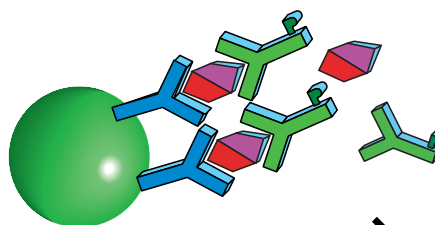
+



Paramagnetic particles coated with anti-CEA MAb



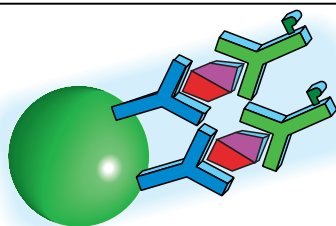
Mix and incubate at 36.5°C for 5 minutes



Sandwich formation



Wash 3 times



+

Add substrate



Incubate 5 minutes

Dioxetane-P



Dioxetane



Read light

Signal produced is directly proportional to the CEA concentration in the sample



CEA

Performance

Access CEA/Abbott IMx CEA Method Comparison

The Access CEA assay was compared with the Abbott IMx CEA method on 288 samples ranging between 0.3 and 920 ng/mL. The comparison between the two methods was analyzed by linear regression using Deming calculation with the following result:

$$\text{Access CEA} = 0.97 \text{ IMx CEA} + 0.52 \quad (r = 0.96)$$

Expected Values

Using the Access CEA assay, CEA concentrations were measured in human serum samples from 301 apparently healthy blood donors, including smokers and non-smokers. This study gave the following results:

	n	0-3.0 ng/mL	3.1-5.0 ng/mL	5.1-10.0 ng/mL	>10 ng/mL
Non-Smokers	151	95.4%	3.9%	0.7%	0.0%
Smokers	150	82.0%	8.7%	8.0%	1.3%
Total	301	88.7%	6.3%	4.3%	0.7%

Characteristics

Sample Type/Size	Serum/10 µL
Time to 1st Result	15 minutes
Analytical Sensitivity	0.1 ng/mL
Calibrator Levels	0, 1, 10, 100, 500, and 1,000 ng/mL
Expected Range	≤5 ng/mL (95% of healthy subjects)
Open Pack Stability	28 days
Calibration Stability	28 days

Ordering Information

Access CEA – 2 packs of 50 tests/pack	33200
Access CEA Calibrators – 6 vials of 2.5 mL/vial	33205
Access CEA QC – 2 levels, 3 vials/level of 2.5 mL/vial	33209
Access CEA Diluent – 1 vial of 4 mL	33206



Africa/Middle East/Eastern Europe: Switzerland, Nyon (41) 22 994 0707. Australia, Gladesville (61) 2 9844 6000. Canada, Mississauga (1) 905 819 1234. China, Beijing (86) 10 6515 6028. Hong Kong (852) 2814 7431, 2814 0481. France, Villepinte (33) 1 49 90 90 00. Germany, Krefeld (49) 2151 33 35. Italy, Milan (39) 02 953921. Japan, Tokyo (81) 3 5404 8424. Latin America (305) 380 4709. Mexico, Mexico City (525) 575 6805. Netherlands, Mijdrecht (31) 297 230630. Singapore (65) 339 3633. South Africa, Johannesburg (27) 11 805 2014. Spain, Madrid (34) 91 728 7900. Sweden, Bromma (46) 8 98 53 20. Switzerland, Nyon 0800 850 810. Taiwan, Taipei (886) 2 2378 3456. UK, High Wycombe (44) 01494 441181. USA, Brea, CA 800 352 3433 714 993 5321.