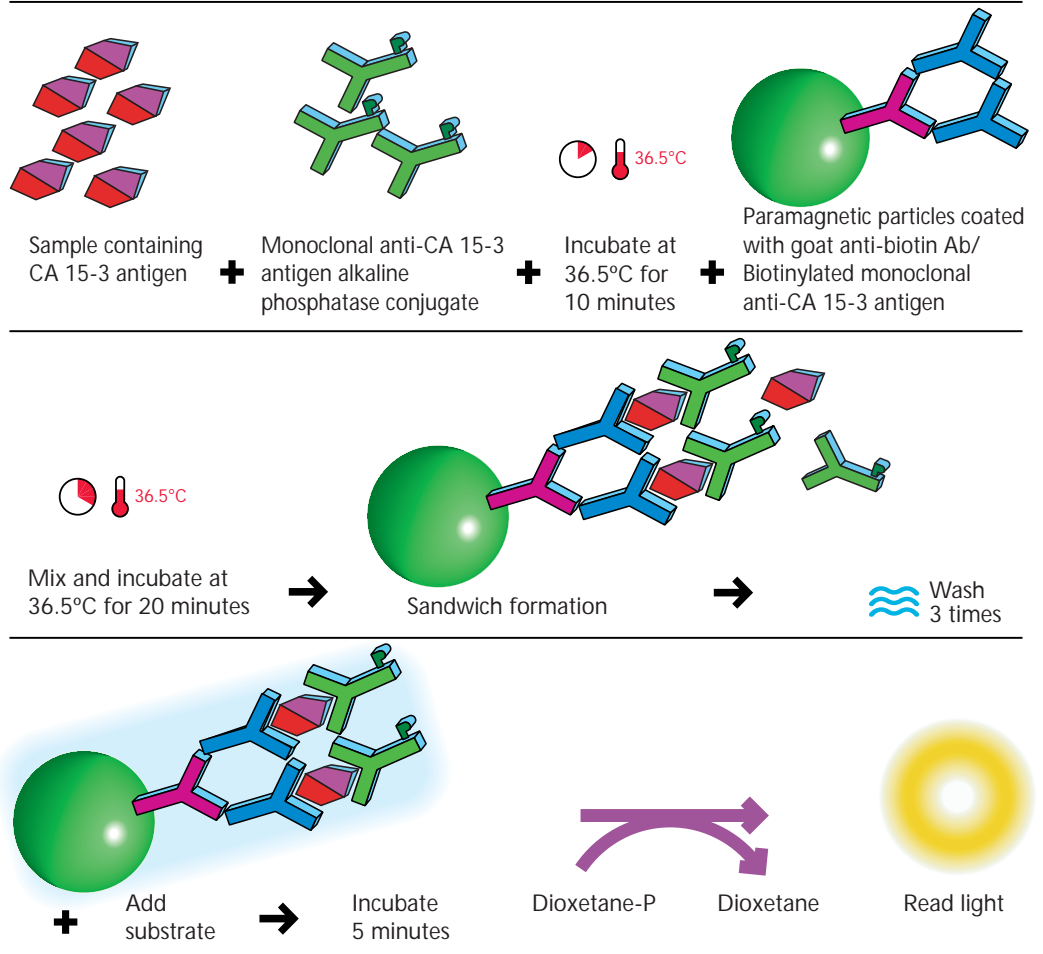


- To aid in the management of breast cancer patients
- For the quantitative determination of CA 15-3 antigen levels in human serum and plasma using the Access® Family of Immunoassay Systems
- Access chemiluminescent technology delivers highly specific and sensitive performance
- Upper reference limit for apparently healthy females: 31.3 U/mL
- Broad dynamic range: 0.5 - 1,000 U/mL
- No hook effect up to 30,000 U/mL
- Open Pack Stability: 56 days
- Calibration Stability: 56 days

2 step sandwich technique



Signal produced is directly proportional to the CA 15-3 antigen concentration in the sample.



BR Monitor (CA 15-3 Antigen)

Performance Access BR Monitor Expected Values

Subject Category	Number of Subjects	0-31.3 U/mL	31.4-60 U/mL	60.1-120 U/mL	> 120 U/mL
Apparently Healthy					
Females < 50 years	152	152	0	0	0
Females ≥ 50 years	152	151	1	0	0
Males	43	43	0	0	0
Malignant Conditions					
Breast Cancer					
Stage I	48	48	0	0	0
Stage II	78	76	2	0	0
Stage III	38	29	4	3	2
Stage IV	40	21	5	4	10
Cervical	24	22	1	0	1
Colon	18	17	1	0	0
Esophageal	9	9	0	0	0
Endometrial	6	6	0	0	0
Fallopian tube	3	2	0	0	1
Gastric/Stomach	43	40	3	0	0
Liver	55	50	2	1	2
Lung	29	22	6	0	1
Pancreatic	14	11	1	1	1
Prostate (males)	51	46	4	1	0
Ovarian	51	40	6	5	0
Vaginal/Vulva	11	10	1	0	0
Uterine	18	13	4	1	0
Non-Malignant Conditions					
Breast	79	76	3	0	0
Colon	43	42	1	0	0
Cystitis	26	23	3	0	0
Gastric/Stomach	37	31	3	3	0
Kidney/Renal Failure	49	45	4	0	0
Liver	45	44	1	0	0
Lung	40	40	0	0	0
Ovarian	25	24	1	0	0
Pelvic Inflammatory disease	23	22	1	0	0
Pregnancy	67	67	0	0	0
Uterine Fibroids	21	20	1	0	0

1. Each laboratory should establish its own reference ranges to assure proper representation of specific populations.
2. The distribution of Access BR Monitor results was determined from a total of 1,244 serum samples from apparently healthy females and females with non-malignant and malignant conditions. Results from 43 apparently healthy males and 51 males with prostate cancer are included in the table.

Characteristics

Sample Type/Size	Serum or plasma (heparin)/10 µL
Time to First Result	41 minutes
Analytical Sensitivity	< 0.5 U/mL
Calibrator Levels	0, 10, 50, 100, 500, 1000 U/mL
Open Pack Stability	56 days
Calibration Stability	56 days
Total Imprecision	< 10% CV

Ordering Information

Access® BR Monitor - 2 packs of 50 tests/pack	387620
Access® BR Monitor Calibrators - 6 vials of 1.5 mL/vial	387647
Access® Sample Diluent A - 1 vial of 4.0 mL	81908



Eastern Europe, Middle East, North Africa: 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 (1) (305) 380 4709. Mexico, Mexico City (525) 575 6805. Netherlands, Mijdrecht (31) 297 230630. Puerto Rico (787) 747 3335. Singapore (65) 6339 3633. South Africa/Sub-Saharan Africa, Johannesburg (27) 11 805 2014. Sweden, Bromma (46) 8 564 85 900. Switzerland, Nyon 0800 850 810. Taiwan, Taipei (886) 2 2378 3456. Turkey, Istanbul (90) 216 309 1900. UK, High Wycombe (44) 01494 441181. USA, Brea, CA (1) 800 352 3433, (1) 714 993 5321.