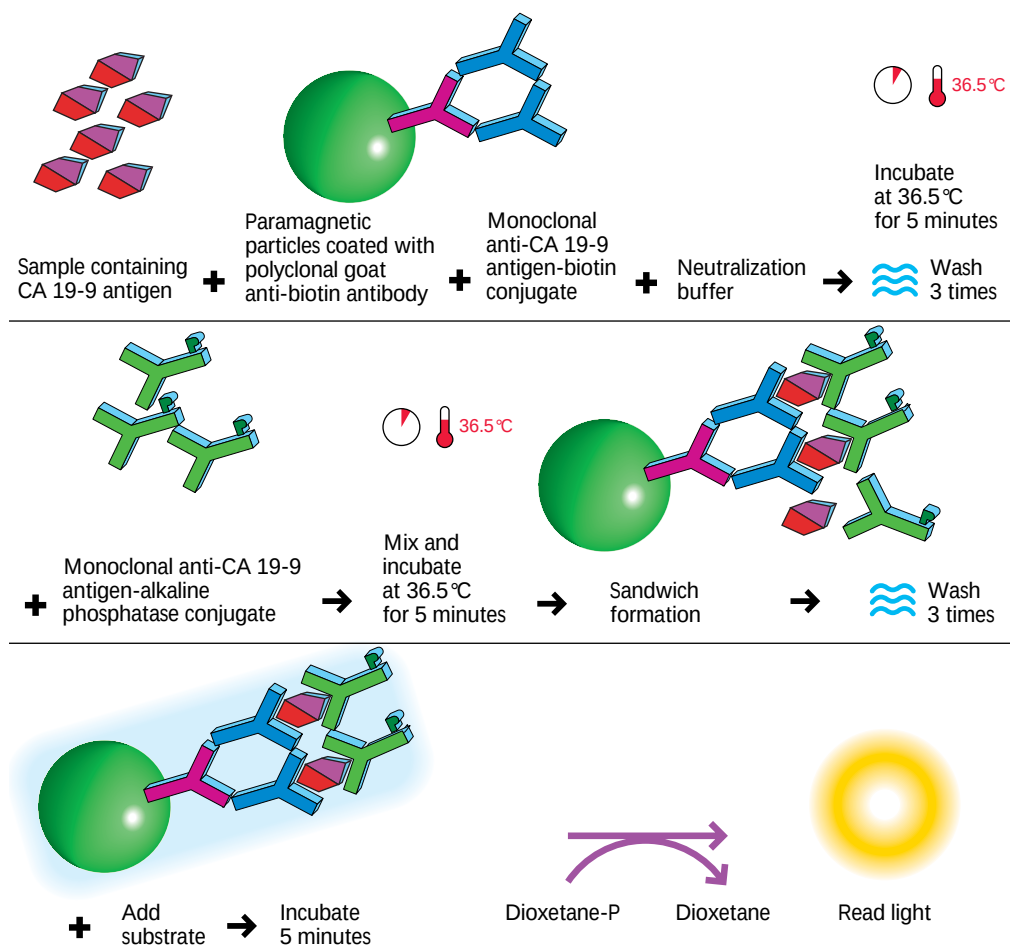


- To aid in the management of pancreatic cancer patients
- For the quantitative determination of CA 19-9 antigen levels in human serum and plasma using the Access® Family of Immunoassay Systems
- Access chemiluminescent technology delivers highly specific and sensitive performance
- Upper reference limit for apparently healthy males and females: 35 U/mL
- Broad dynamic range: 0.8 - 2000 U/mL
- No hook effect up to 800,000 U/mL
- Open Pack Stability: 56 days
- Calibration Stability: 56 days

2 step
sandwich
technique



Signal produced is directly proportional to the CA 19-9 antigen concentration in the sample.



GI Monitor (CA 19-9 Antigen)

Performance Access GI Monitor Expected Values

Subject Category	Number of Subjects	0-35 U/mL	35.1-70 U/mL	70.1-100 U/mL	> 100 U/mL
Apparently Healthy					
Females	150	141	8	1	0
Males	141	134	6	1	0
Malignant Conditions*					
Pancreas	40	10	2	5	23
Biliary/Gallbladder	25	13	0	0	12
Breast	37	35	0	1	1
Gastrointestinal	142	102	21	0	19
Genitourinary	111	95	9	4	3
Liver	84	67	9	0	8
Lung	70	52	11	1	6
Non-Malignant Conditions*					
Pancreas	100	90	9	0	1
Chronic Heart Disease/Hypertension	85	81	4	0	0
Gastrointestinal	147	140	7	0	0
Genitourinary	190	174	15	1	0

*including treated subjects

1. Each laboratory should establish its own reference ranges to assure proper representation of specific populations.
2. The distribution of Access GI Monitor results was determined from a total of 1,322 serum samples from apparently healthy males and females and from males and females with non-malignant and malignant conditions.

Characteristics

Sample Type/Size	Serum or plasma (heparin)/10 µL
Time to First Result	24 minutes
Analytical Sensitivity	0.8 U/mL
Calibrator Levels	0, 30, 90, 300, 900, 2000 U/mL
Open Pack Stability	56 days
Calibration Stability	56 days
Total Imprecision	< 10% CV

Ordering Information

Access® GI Monitor - 2 packs of 50 tests/pack	387687
Access® GI Monitor Calibrators - 6 vials of 2.5 mL/vial	387688
Access® Sample Diluent A - 1 vial of 4.0 mL	81908



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