Access
Immunoassay Systems

GI MONITOR

REF 387687

Warning

The concentration of CA 19-9 antigen in a given specimen determined with assays from different manufacturers can vary due to differences in assay methods and reagent specificity. The results reported by the laboratory to the physician must include the identity of the CA 19-9 antigen assay used. Values obtained with different assay methods cannot be used interchangeably. If, in the course of monitoring a patient, the assay method used for determining CA 19-9 antigen values is changed, additional sequential testing should be carried out to confirm baseline values.

Patients must possess the ability to express the Lewis blood group antigen or they will be unable to produce the CA 19-9 antigen even in the presence of proven malignancy. A patient with a positive genotype for the Lewis antigen may produce varying levels of CA 19-9 antigen. Phenotyping for the presence of the Lewis blood group antigen may be insufficient to detect true Lewis antigen negative individuals.

Intended Use

The Access GI Monitor assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of CA 19-9 antigen levels in human serum and plasma using the Access Immunoassay Systems.

Summary and Explanation

The CA 19-9 antigen, a Lewis blood group-related mucin, is a tumor-associated antigen synthesized by normal human pancreatic and biliary ductular cells, and gastric, colonic, endometrial and salivary epithelia.[1,2] Typically, only a minimal amount of the CA 19-9 antigen is present in the blood of normal subjects or subjects with benign disorders.

Initially found in colorectal cancer patients, the CA 19-9 antigen has also been identified in patients with pancreatic, bile duct, hepatocellular, stomach, and esophageal cancers. Non-cancerous conditions that may elevate CA 19-9 antigen levels include cirrhosis, cholangitis, hepatitis, pancreatitis, and non-malignant gastrointestinal diseases.[2,3,4,5,6]

CA 19-9 antigen levels may be used as an aid in monitoring the response to therapy. The presence of persistently rising CA 19-9 antigen levels may be correlated with disease progression. Persistently elevated CA 19-9 antigen levels may indicate poor response to therapy, whereas decreasing CA 19-9 antigen levels may indicate a positive therapeutic response.[7,8]

The Access GI Monitor assay is not recommended as a screening tool. A value below the cutoff limit does not indicate the absence of disease. Other clinically acceptable tests and procedures should also be considered in the monitoring of disease and good patient management.

Principles of the Procedure

The Access GI Monitor assay is a two-site immunoenzymatic ("sandwich") assay. A sample is added to a reaction vessel along with paramagnetic particles coated with polyclonal goat anti-biotin antibody, mouse monoclonal–biotin conjugate, and a buffered protein solution. After incubation in a reaction vessel, separation in a magnetic field and washing remove materials not bound to the solid phase. A monoclonal-alkaline phosphatase conjugate is then added. After incubation in a reaction vessel, materials bound to the solid phase are held in a magnetic field while unbound materials are washed away. Then, the chemiluminescent substrate Lumi-Phos* 530 is added to the vessel and light generated by the reaction is measured with a luminometer. The light production is directly proportional to the concentration of

CA 19-9 antigen in the sample. The amount of analyte in the sample is determined from a stored, multi-point calibration curve.

Product Information

Access GI Monitor Reagent Pack

Cat. No. 387687: 100 determinations, 2 packs, 50 tests/pack

- Provided ready to use.
- Store upright and refrigerate at 2 to 10°C.
- Refrigerate at 2 to 10°C for a minimum of two hours before use on the instrument.
- Stable until the expiration date stated on the label when stored at 2 to 10°C.
- Stable at 2 to 10°C for 56 days after initial use.
- Signs of possible deterioration are a broken elastomeric layer on the pack or control values out of range.
- If the reagent pack is damaged (i.e., broken elastomer), discard the pack.
- All antisera are polyclonal unless otherwise indicated.

R1a:	Paramagnetic particles, coated with goat polyclonal anti-biotin antibody, bovine serum albumin, < 0.1% sodium azide and 0.1% ProClin** 300.
R1b:	Mouse monoclonal anti-CA 19-9 antigen-alkaline phosphatase (bovine) conjugate, bovine serum albumin, < 0.1% sodium azide and 0.1% ProClin 300.
R1c:	Mouse monoclonal anti-CA 19-9 antigen-biotin conjugate, bovine serum albumin, < 0.1% sodium azide and 0.1% ProClin 300.
R1d:	Buffered protein solution (bovine, goat, mouse), < 0.1% sodium azide and 0.1% ProClin 300.

Warnings and Precautions

- For *in vitro* diagnostic use.
- Patient samples and blood-derived products may be routinely processed with minimum risk using the procedure described. However, handle these products as potentially infectious according to universal precautions and good clinical laboratory practices, regardless of their origin, treatment, or prior certification. Use an appropriate disinfectant for decontamination. Store and dispose of these materials and their containers in accordance with local regulations and guidelines.
- Human source material used in the preparation of the reagent has been tested and found negative or non-reactive for Hepatitis B, Hepatitis C (HCV), and Human Immunodeficiency Virus (HIV-1 and HIV-2). Because no known test method can offer complete assurance that infectious agents are absent, handle reagents and patient samples as if capable of transmitting infectious disease.[9]
- Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal of liquids, flush with a large volume of water to prevent azide build-up.[10]
- Xi. Irritant: 0.1% ProClin 300.

R 43: May cause sensitization by skin contact.

S 28-37: After contact with skin, wash immediately with plenty of soap and water. Wear suitable gloves.

- The Material Safety Data Sheet (MSDS) is available upon request.

Specimen Collection and Preparation

1. Serum and plasma (heparin) are the recommended samples.
2. Observe the following recommendations for handling, processing, and storing blood samples:[11]

- Collect all blood samples observing routine precautions for venipuncture.
- Allow serum samples to clot completely before centrifugation.
- Keep tubes stoppered at all times.
- Within two hours after centrifugation, transfer at least 500 µL of cell-free sample to a storage tube. Tightly stopper the tube immediately.
- Store samples tightly stoppered at room temperature (15 to 30°C) for no longer than eight hours.
- If the assay will not be completed within eight hours, refrigerate the samples at 2 to 8°C.
- If the assay will not be completed within 48 hours, or for shipment of samples, freeze at -20°C or colder.
- Thaw samples only once.

3. Use the following guidelines when preparing specimens:
   - Ensure residual fibrin and cellular matter has been removed prior to analysis.
   - Follow blood collection tube manufacturer's recommendations for centrifugation.
4. Each laboratory should determine the acceptability of its own blood collection tubes and serum separation products. Variations in these products may exist between manufacturers and, at times, from lot-to-lot.
5. Avoid assaying lipemic and/or hemolyzed samples.

Materials Provided

R1 Access GI Monitor Reagent Packs

Materials Required But Not Provided

1. Access GI Monitor Calibrators
   Provided at zero and approximately 30, 90, 300, 900 and 2000 U/mL
   Cat. No. 387688
2. Quality Control (QC) materials: commercial control material
3. Access Sample Diluent A
   Vial Cat. No. 81908
   Diluent Pack Cat. No. A79783 (For use with the UniCel DxI system onboard dilution feature.)
4. Access Substrate
   Cat. No. 81906
5. **Access, Access 2, SYNCHRON LXi:**
   Access Wash Buffer II, Cat. No. A16792
   UniCel DxI:
   UniCel DxI Wash Buffer II, Cat. No. A16793

Procedural Comments

1. Refer to the appropriate system manuals and/or Help system for a specific description of installation, start-up, principles of operation, system performance characteristics, operating instructions, calibration procedures, operational limitations and precautions, hazards, maintenance, and troubleshooting.
2. Mix contents of new (unpunctured) reagent packs by gently inverting pack several times before loading on the instrument. Do not invert open (punctured) packs.
3. Use ten (10) µL of sample for each determination in addition to the sample container and system dead volumes. Use fifty (50) µL of sample in addition to the sample container and system dead volumes for each determination run with the DxI system onboard dilution feature. Refer to the appropriate system manuals and/or Help system for the minimum sample volume required.
4. The system default unit of measure for sample results is U/mL.

Procedure

Refer to the appropriate system manuals and/or Help system for information on managing samples, configuring tests, requesting tests, and reviewing test results.

Calibration Details

An active calibration curve is required for all tests. For the Access GI Monitor assay, calibration is required every 56 days. Refer to the appropriate system manuals and/or Help system for information on calibration theory, configuring calibrators, calibrator test request entry, and reviewing calibration data.

Quality Control

Quality control materials simulate the characteristics of patient samples and are essential for monitoring the system performance of immunochemical assays. Because samples can be processed at any time in a "random access" format rather than a "batch" format, quality control materials should be included in each 24-hour time period.[12] Include commercially available quality control materials that cover at least two levels of analyte. More frequent use of controls or the use of additional controls is left to the discretion of the user based on good laboratory practices or laboratory accreditation requirements and applicable laws. Follow manufacturer's instructions for reconstitution and storage. Each laboratory should establish mean values and acceptable ranges to assure proper performance. Quality control results that do not fall within acceptable ranges may indicate invalid test results. Examine all test results generated since obtaining the last acceptable quality control test point for this analyte. Refer to the appropriate system manuals and/or Help system for information about reviewing quality control results.

Results

Patient test results are determined automatically by the system software using a smoothing spline math model. The amount of analyte in the sample is determined from the measured light production by means of the stored calibration data. Patient test results can be reviewed using the appropriate screen. Refer to the appropriate system manuals and/or Help system for complete instructions on reviewing sample results.

Limitations of the Procedure

1. The Access GI Monitor results should be interpreted in light of the total clinical presentation of the patient, including: symptoms, clinical history, data from additional tests, and other appropriate information.
2. Serum or plasma CA 19-9 antigen concentrations should not be interpreted as absolute evidence for the presence or absence of cancer. Elevated concentrations may be observed in the serum or plasma of patients with benign conditions or other non-cancer disorders, as well as in pancreatic cancer and other malignant diseases. The Access GI Monitor assay should not be used as a cancer screening test.
3. Patients must possess the ability to express the Lewis blood group antigen or they will be unable to produce the CA 19-9 antigen even in the presence of proven malignancy. A patient with a positive genotype for the Lewis antigen may produce varying levels of CA 19-9 antigen. Phenotyping for the presence of the Lewis blood group antigen may be insufficient to detect true Lewis antigen negative individuals.
4. Samples can be accurately measured within the analytic range of the lower limit of detection and the highest calibrator value (approximately 0.8–2000 U/mL).
   - If a sample contains less than the lower limit of detection for the assay, report the results as less than that value (i.e., < 0.8 U/mL). When the DxI system onboard dilution feature is used, the system will report results as less than 1700 U/mL.
   - If a sample contains more than the stated value of the highest Access GI Monitor Calibrator (S5), report the result as greater than that value (i.e., > 2000 U/mL). Alternatively, dilute one volume of sample with nine volumes of Access Sample Diluent A. Refer to the appropriate system manuals and/or Help system for instructions on entering a sample dilution in a test request. The system reports the results adjusted for the dilution.

     The DxI system onboard dilution feature automates the dilution process, using one volume of sample with nine volumes of Access Sample Diluent A, allowing samples to be

quantitated up to approximately 20,000 U/mL. The system reports the results adjusted for the dilution.

5. For assays employing antibodies, the possibility exists for interference by heterophile antibodies in the patient sample. Patients who have been regularly exposed to animals or have received immunotherapy or diagnostic procedures utilizing immunoglobulins or immunoglobulin fragments may produce antibodies, e.g. HAMA, that interfere with immunoassays. Additionally, other heterophile antibodies such as human anti-goat antibodies may be present in patient samples.[13,14]
   Such interfering antibodies may cause erroneous results. Carefully evaluate the results of patients suspected of having these antibodies.
6. The Access GI Monitor assay does not demonstrate any "hook" effect up to 800,000 U/mL.

Expected Values

1. Each laboratory should establish its own reference ranges to assure proper representation of specific populations.
2. The distribution of Access GI Monitor results, presented below were 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.

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

Clinical Performance

Upper Reference Limit (URL)

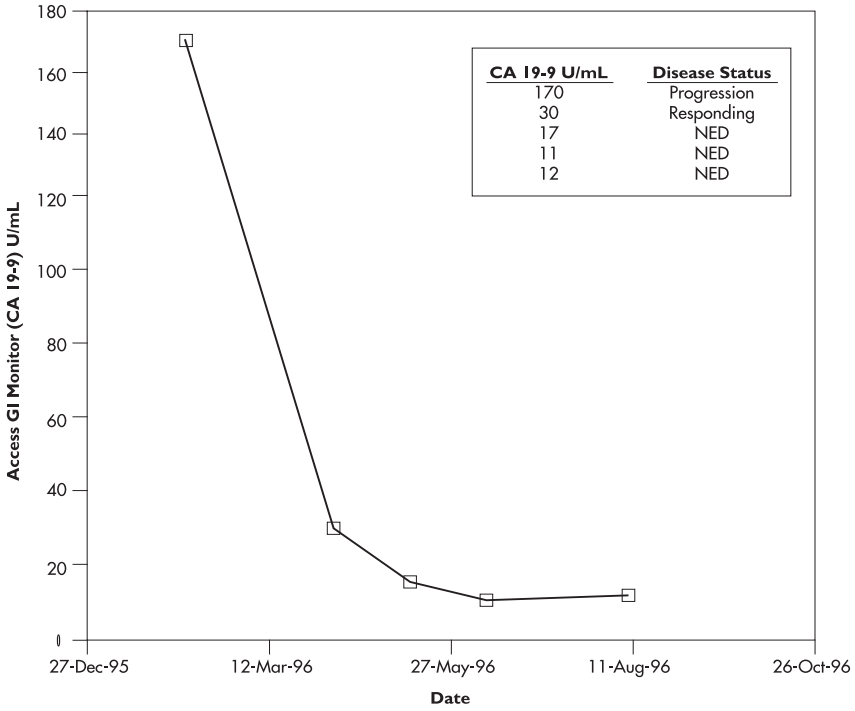
The upper reference limit (URL) for the Access GI Monitor assay was determined using a total of 291 serum samples from apparently healthy females (150) and males (141). The 95th percentile, 35 U/mL CA 19-9 antigen, was set as the URL for the Access GI Monitor assay results for the combined female and male population. The distribution of Access GI Monitor results for this apparently healthy population is provided in the Expected Values table above.

Monitoring of Patients Diagnosed With Pancreatic Cancer

In this study, a total of 255 serum samples were obtained from 63 subjects (ages ranging from 28 to 83 years) who were diagnosed with pancreatic cancer (stages I to IV). These subjects were monitored over the course of disease, ranging from 21 days to 66 months.

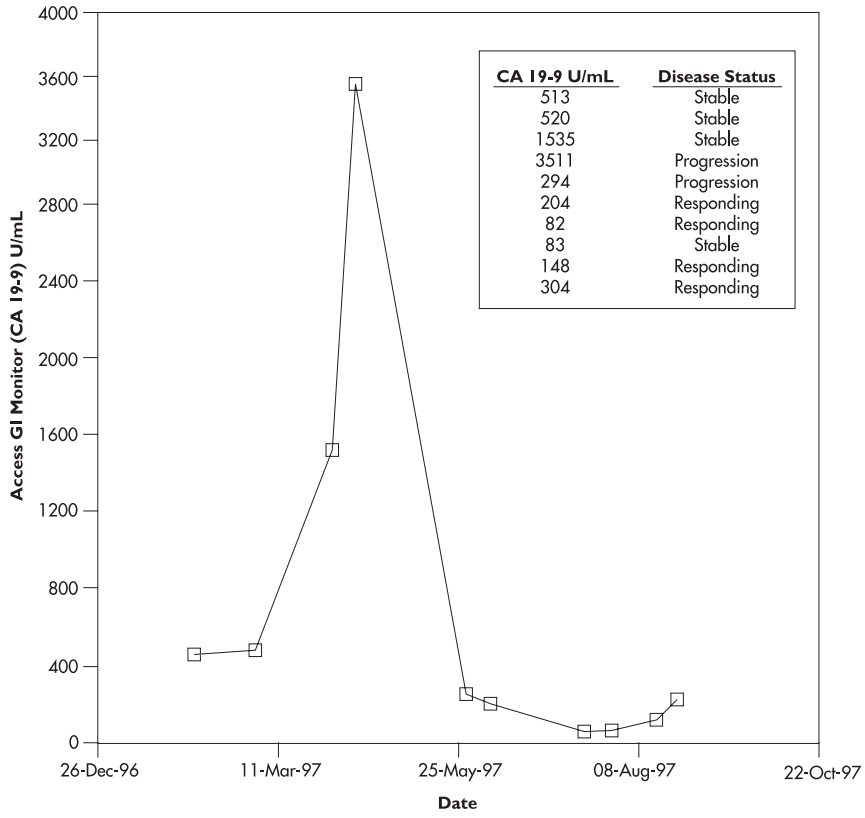
Below are three examples showing serial monitoring profiles for the Access GI Monitor CA 19-9 antigen values and the clinical status.

Pancreatic Cancer Serial Monitoring
Patient A

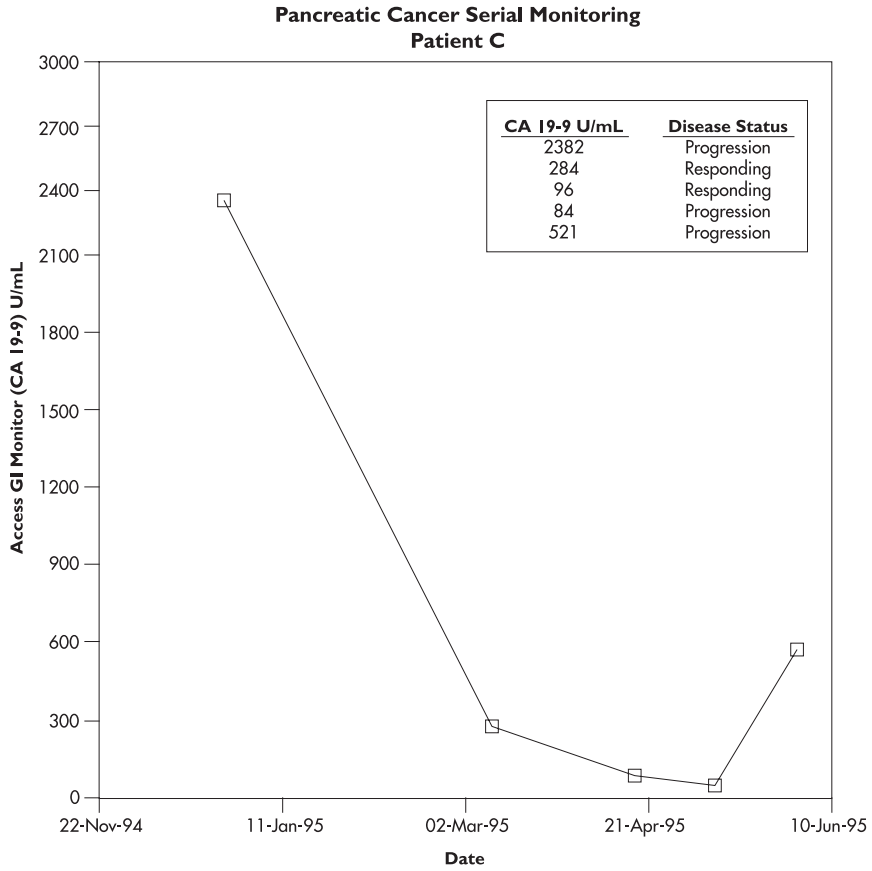


CA 19-9 U/mL	Disease Status
170	Progression
30	Responding
17	NED
11	NED
12	NED

Pancreatic Cancer Serial Monitoring
Patient B



CA 19-9 U/mL	Disease Status
513	Stable
520	Stable
1535	Stable
3511	Progression
294	Progression
204	Responding
82	Responding
83	Stable
148	Responding
304	Responding



Based on regression models, a 20% Least Significant %Change (LS %Change) was selected to cover the imprecision across the range of Access GI Monitor concentrations. The LS %Change represents the minimum magnitude change between two serial CA 19-9 antigen measurements that could not be attributed to assay variation or noise. The LS %Change corresponds to 2.5 times the %CV (coefficient of variation) for imprecision, for the Access GI Monitor assay.

The effectiveness of CA 19-9 antigen measurements as an aid in monitoring disease status in patients diagnosed with pancreatic cancer was determined by assessing changes in CA 19-9 antigen levels in serial sets (pairs) with change in disease status. Of the 63 serial monitored subjects, ten (10) of the subjects were excluded from these evaluations as they were presumed to be CA 19-9 antigen non-expressors with CA 19-9 antigen concentrations ≤ 10 U/mL for all available serial blood draws. The remaining 53 pancreatic cancer subjects, from the serial monitoring study, were analyzed using one serial set (two sequential visits per set) per subject. In this evaluation, disease status was classified as "Progression" or "No Progression", with "No Progression" consisting of "stable", "responding", or "no evidence of disease (NED)" between two consecutive serial draws. The results from these analyses, on a per patient basis, are presented below.

Association of CA 19-9 Antigen Concentrations vs. Disease Status (Per Patient Basis)

Access GI Monitor	Change in Clinical Status		Total
Marker Change	**Progression**	**No Progression**	
20% Increase	25	11	36
No Increase	7	10	17
Total	32	21	53
Access GI Monitor		**95% Confidence Interval**	
Positive Concordance	78.1%	61.2%	89.0%
Negative Concordance	47.6%	28.3%	67.6%
Total Concordance	66.0%	52.6%	77.3%

The effectiveness of CA 19-9 antigen measurements as an aid in monitoring disease status in patients diagnosed with pancreatic cancer was also determined by assessing changes in CA 19-9 antigen levels in serial sets (sequential visit pairs) with changes in disease status. Samples from the 53 patients from the serial monitoring study, for a total of 168 serial sets (sequential visit pairs), were further analyzed for %change in CA 19-9 antigen concentrations across serial sets and disease status. In this evaluation disease status, between two consecutive serial draws, was classified as "Progression" or "No Progression". The distribution of results across the three disease classifications relative to the 20% LS %Change, on a per sample basis, are presented below for the Access GI Monitor assay.

% Change in CA 19-9 Antigen Concentrations vs. Disease Status Based on 20% Least Significant % Change (Per Sample Basis)

Access GI Monitor	Change in Disease State		Total
Change in CA 19-9 Antigen	**Progression**	**No Progression**	
Significant change > 20%	41	37	78
No Change ≤ 20%	28	62	90
Total	69	99	168
Access GI Monitor		**95% Confidence Interval**	
Positive Concordance	59.4%	47.7%	70.2%
Negative Concordance	62.6%	52.8%	71.5%
Total Concordance	61.3%	58.8%	68.3%

Specific Performance Characteristics

Methods Comparison

A comparison of 405 values using the Access GI Monitor assay on the Access Immunoassay system and a commercially available radioimmunoassay kit gave the following statistical data using Deming calculations:

n	Range of Observations (U/mL)	Intercept (U/mL)	Slope	Correlation Coefficient (r)
405	0–236.0	2.5726	0.9569	0.9007

Sample Type Comparison

A comparison of 80 matched serum and lithium heparin plasma samples using the Access GI Monitor assay on the Access Immunoassay system gave the following statistical data using Deming calculations:

n	Range of Observations (U/mL)	Intercept (U/mL)	Slope	Correlation Coefficient (r)
80	0–1650.9	-0.5002	0.9842	0.9995

Dilution Recovery (Linearity)

Multiple dilutions of three samples containing various CA 19-9 antigen levels with Access Sample Diluent A resulted in the following data:

Sample 1	Expected Concentration (U/mL)	Determined Concentration (U/mL)	Recovery (%)
Neat	1202.7	–	100
1:2	601.3	536.3	89.2
1:4	300.7	282.7	94.0
1:8	150.3	142.2	94.6
1:16	75.2	68.4	91.0
1:32	37.6	35.6	94.7
1:64	18.8	17.3	92.0
		Mean % Recovery	**92.6**

Sample 2	Expected Concentration (U/mL)	Determined Concentration (U/mL)	Recovery (%)
Neat	1382.1	–	100
1:2	691.1	748.2	108.3
1:4	345.5	356.6	103.2
1:8	172.8	169.8	98.3
1:16	86.4	83.7	96.9
1:32	43.2	40.7	94.2
1:64	21.6	20.7	95.8
		Mean % Recovery	**99.5**

Sample 3	Expected Concentration (U/mL)	Determined Concentration (U/mL)	Recovery (%)
Neat	1239.1	–	100
1:2	619.6	601.5	97.1
1:4	309.8	288.3	93.1
1:8	154.9	137.2	88.6
1:16	77.4	70.5	91.1
1:32	38.7	37.8	97.7
1:64	19.4	19.6	101.0
		Mean % Recovery	**94.8**

Imprecision

This assay exhibits total imprecision of less than 10% across the assay range. One study, using commercially available human serum based control material generating a total of 20 assays, 2 replicates per assay, over 20 days provided the following data, analyzed via analysis of variance (ANOVA).[15,16]

Sample	Grand Mean (n=40) (U/mL)	Within Run (%CV)	Between Run (%CV)	Total Imprecision (%CV)
Level 1	17.6	6.4	5.7	8.9
Level 2	110.5	2.2	2.7	3.5
Level 3	584.6	1.7	2.5	3.1
Level 4	1664.5	1.8	2.4	3.0

Analytical Specificity/Interferences

Samples containing up to 50 mg/dL hemoglobin, 60 mg/dL bilirubin, 1000 mg/dL triglycerides (triolein) or 9 g/dL protein (human serum albumin) do not affect the concentration of CA 19-9 antigen assayed.

The following table describes the cross-reactivity of the assay with common chemotherapeutic agents and other potential interferents.

Substance	Concentration Added	Expected (U/mL)	Observed (U/mL)	Mean % Recovery
5Fluoruracil (Adrucil)	1 mg/mL	8.4	8.3	99
Acetominophen (Tylenol)	0.2 mg/mL	8.9	8.8	99
Acetylsalicyclic acid (aspirin)	0.5 mg/mL	9.4	8.8	94
Adriamycin (Doxorubicin – HCL)	0.1 mg/mL	8.7	8.5	98
Amethopterin Hydrate (Methotrexate)	4.5 mg/mL	9.3	9.1	98
Aminoglutethimide	0.4 mg/mL	8.6	8.6	100
Caffeine	0.1 mg/mL	8.5	8.7	102
Cisplatin – Dichloride	1 mg/mL	8.9	8.2	92
Cyclophosphamide (Cytoxan)	0.25 mg/mL	9.4	9.4	100
Cyclosporin A	2.97×10^{-6} mg/mL	9.8	9.2	94
Digoxin	5.0×10^{-6} mg/mL	9.7	9.4	97
Folinic Acid (Leucovorin)	1.1 mg/mL	9.1	9.4	103
Gentamicin– Sulphate Salt	0.12 mg/mL	9.0	9.6	107
Heparin	50 U/mL	8.3	9.0	108
Lidocaine Hydrochloride	0.06 mg/mL	8.5	8.8	104
Lithium Carbonate (Eskalith)	0.035 mg/mL	9.0	8.3	92
Mitomycin C	0.006 mg/mL	9.2	10.1	110
Novatrone (Mitoxanntrone)	0.5 mg/mL	8.3	8.1	98
Paclitaxel	3.5×10^{-6} mg/mL	9.4	9.2	98
Propanolol - HCL (Inderal)	5.0×10^{-6} mg/mL	9.0	8.7	97
Quinidine gluconate (Duraguin, Quinaglute)	0.05 mg/mL	9.0	8.9	99
Salicylate (Salicylic acid - Sodium Salt)	0.5 mg/mL	8.9	8.7	98
Tamoxifen - Citrate Salt	0.13 mg/mL	9.3	8.6	92
Theophyline (Aminophyline)	0.25 mg/mL	8.9	8.8	99
Tobramycin - Sulfate Salt	0.015 mg/mL	9.1	9.4	103

Analytical Sensitivity

The lowest detectable level of CA 19-9 antigen distinguishable from zero (Access GI Monitor Calibrator S0) with 95% confidence is 0.8 U/mL. This value is determined by processing a complete six point calibration curve, controls, and 10 replicates of the zero calibrator in multiple assays. The analytical sensitivity value is calculated from the curve at the point that is two standard deviations from the fitted zero calibrator signal.

Access
Immunoassay Systems

GI MONITOR CALIBRATORS

REF 387688

Warning

The concentration of CA 19-9 antigen in a given specimen determined with assays from different manufacturers can vary due to differences in assay methods and reagent specificity. The results reported by the laboratory to the physician must include the identity of the CA 19-9 antigen assay used. Values obtained with different assay methods cannot be used interchangeably. If, in the course of monitoring a patient, the assay method used for determining of CA 19-9 antigen values is changed, additional sequential testing should be carried out to confirm baseline values.

Intended Use

The Access GI Monitor Calibrators are intended to calibrate the Access GI Monitor assay for the quantitative determination of CA 19-9 antigen levels in human serum and plasma using the Access Immunoassay Systems.

Summary and Explanation

Quantitative assay calibration is the process by which samples with known analyte concentrations (i.e., assay calibrators) are tested like patient samples to measure the response. The mathematical relationship between the measured responses and the known analyte concentrations establishes the calibration curve. This mathematical relationship, or calibration curve, is used to convert RLU (Relative Light Unit) measurements of patient samples to specific quantitative analyte concentrations.

Traceability

The measurand (analyte) in the Access GI Monitor Calibrators is traceable to the manufacturer's working calibrators. Traceability process is based on EN ISO 17511.

The assigned values were established using representative samples from this lot of calibrator and are specific to the assay methodologies of the Access reagents. Values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

Product Information

Access GI Monitor Calibrators

Cat. No. 387688: S0–S5, 2.5 mL/vial

- Provided ready to use.
- Freeze upon receipt at -20°C or colder.
- Mix contents by gently inverting before use. Avoid bubble formation.
- Stable until the expiration date stated on the label when stored at -20°C or colder.
- After initial use, the thawed vials are stable at 2 to 10°C for 90 days unless the expiration date transpires prior to the 90 day limit. Label the vials with the date of thaw or the date of expiration.
- Return calibrators to 2 to 10°C after each use. Do not refreeze opened vials.
- Signs of possible deterioration are control values out of range.
- Refer to calibration card for exact concentrations.

S0:	Buffered bovine serum albumin (BSA), < 0.1% sodium azide and 0.5% ProClin** 300.
S1, S2, S3, S4, S5:	CA 19-9 antigen at levels of approximately 30, 90, 300, 900 and 2000 U/mL, in buffered BSA, < 0.1% sodium azide and 0.5% ProClin 300.
Calibration Card:	1

Warnings and Precautions

- For *in vitro* diagnostic use.
- Patient samples and blood-derived products may be routinely processed with minimum risk using the procedure described. However, handle these products as potentially infectious according to universal precautions and good clinical laboratory practices, regardless of their origin, treatment, or prior certification. Use an appropriate disinfectant for decontamination. Store and dispose of these materials and their containers in accordance with local regulations and guidelines.
- Human source material used in the preparation of the reagent has been tested and found negative or non-reactive for Hepatitis B, Hepatitis C (HCV), and Human Immunodeficiency Virus (HIV-1 and HIV-2). Because no known test method can offer complete assurance that infectious agents are absent, handle reagents and patient samples as if capable of transmitting infectious disease.[9]
- Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal of liquids, flush with a large volume of water to prevent azide build-up.[10]
- Xi. Irritant: 0.5% ProClin 300.

R 43: May cause sensitization by skin contact.
S 28-37: After contact with skin, wash immediately with plenty of soap and water. Wear suitable gloves.

- The Material Safety Data Sheet (MSDS) is available upon request.

Procedure

Refer to the appropriate system manuals and/or Help system for information on calibration theory, configuring calibrators, calibrator test request entry, and reviewing calibration data.

Calibration Details

The Access GI Monitor Calibrators are provided at six levels - zero and approximately 30, 90, 300, 900 and 2000 U/mL. Assay calibration data are valid up to 56 days.

Calibrators run in duplicate.

Limitations of the Procedure

If there is evidence of microbial contamination or excessive turbidity in a reagent, discard the vial.

Access
Immunoassay Systems

SAMPLE DILUENT A

REF 81908 (Vial)

REF A79783 (Diluent Pack)

Intended Use

The Access Sample Diluent A is intended for use with Access assays to dilute patient samples containing analyte concentrations greater than the analyte specific S5 calibrator.

Summary and Explanation

The analyte level in patient samples may exceed the level of the specific S5 calibrator. If a quantitative value is required, it will be necessary to dilute the samples in order to determine the analyte concentration.

Product Information

Access Sample Diluent A

Cat. No. 81908: 4 mL/vial

- Provided ready to use.
- Allow the contents to stand for 10 minutes at room temperature.
- Mix gently by inverting before use. Avoid bubble formation.
- Stable until the expiration date stated on the vial label when stored at 2 to 10°C.

Diluent:	Buffered BSA matrix with surfactant, < 0.1% sodium azide, 0.5% ProClin** 300.

Cat. No. A79783: 2 diluent packs, 32.9 mL/pack

- Provided ready to use.
- Store upright and refrigerate at 2 to 10°C.
- Refrigerate at 2 to 10°C for a minimum of two hours before use on the instrument.
- Stable until the expiration date stated on the label when stored at 2 to 10°C.
- Stable at 2 to 10°C for 56 days after initial use of each well.
- Signs of possible deterioration are a broken elastomeric layer on the pack or control values out of range.
- If the diluent pack is damaged (i.e., broken elastomer), discard the pack.

R1a - R1e:	Buffered BSA matrix with surfactant, < 0.1% sodium azide, 0.5% ProClin 300.

Warnings and Precautions

- For *in vitro* diagnostic use.
- Patient samples and blood-derived products may be routinely processed with minimum risk using the procedure described. However, handle these products as potentially infectious according to universal precautions and good clinical laboratory practices, regardless of their origin, treatment, or prior certification. Use an appropriate disinfectant for decontamination. Store and dispose of these materials and their containers in accordance with local regulations and guidelines.
- Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal of liquids, flush with a large volume of water to prevent azide build-up.[10]

- Xi. Irritant: 0.5% ProClin 300.

R 43: May cause sensitization by skin contact.
S 28-37: After contact with skin, wash immediately with plenty of soap and water. Wear suitable gloves.

- The Material Safety Data Sheet (MSDS) is available upon request.

Procedure

Samples can be accurately measured within the analytic range of the lower limit of detection and the highest calibrator value of the specific assay. If a sample contains more analyte than the stated value of the S5 calibrator, dilute the sample following dilution instructions in the specific assay labeling under "Limitations of the Procedure" in the reagent pack section. Refer to the appropriate system manuals and/or Help system for instructions on how to enter a sample dilution in a test request.

Limitations of the Procedure

If there is evidence of microbial contamination or excessive turbidity in the reagent, discard the vial.

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