



DEC 29 2003

## 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K033038

### Submitter's Name and Address

Beckman Coulter, Inc.  
1000 Lake Hazeltine Drive  
Chaska, MN 55318  
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Contact: Brent Taber

Date Prepared: December 8, 2003

### Device Names

Proprietary Name: GI Monitor and GI Monitor Calibrators on the Access® Immunoassay Systems

Common Name: Immunological test for 116NS19-9 Antibody Defined Antigen (CA19-9)

Classification Name: System, Test, Carbohydrate Antigen (CA 19-9), for Monitoring and Management of Pancreatic Cancer

### Predicate Device

Fujirebio Diagnostics CA 19-9 RIA  
Fujirebio Diagnostics, Inc.  
201 Great Valley Parkway  
Malvern, PA 19355

510(k) Number: k020566

### Device Description

The Access GI Monitor reagents, calibrators, and the Access Immunoassay Analyzers (Access, Access 2, Synchron LXi 725, and UniCel Dxl 800) comprise the Access Immunoassay Systems for the quantitative determination of CA 19-9 antigen in human serum and plasma.



### 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. This device is indicated for use in the measurement of CA 19-9 antigen to aid in the management of pancreatic cancer patients. The test is useful as an aid in monitoring of disease status in those patients having confirmed pancreatic cancer whose serum CA 19-9 antigen levels exceed 10 U/mL, the cut-off value for individuals who are Lewis blood group antigen negative. Serial testing for patient CA 19-9 antigen concentrations should be used in conjunction with other clinical methods used for monitoring pancreatic cancer.

### Comparison of Technological Characteristics

Attribute	Fujirebio Diagnostics CA 19-9 RIA	Access GI Monitor
Intended Use	For the measurement of CA 19-9 antigen in human serum and plasma	For the measurement of CA 19-9 antigen in human serum and plasma
Assay Principles	Utilizes the binding of CA 19-9 to a specific monoclonal antibody in a manual, two-site "sandwich" radioimmunoassay; Utilizes <sup>125</sup> I conjugated to monoclonal antibody	Utilizes the binding of CA 19-9 to a specific monoclonal antibody in an automated, two-site "sandwich" enzyme immunoassay; Utilizes alkaline phosphatase enzyme conjugated to monoclonal antibody
Solid Support	Polystyrene beads	Paramagnetic particles
Detection System	Utilizes <sup>125</sup> I conjugated to monoclonal antibody; Measures bound radioactivity with a gamma counter	Utilizes dioxetane-based chemiluminescent substrate; Measures light production from a chemiluminescent reaction
Calibrators	Liquid calibrators prepared from defibrinated normal human plasma with CA 19-9 antigen at specified levels	Liquid calibrators prepared from buffered bovine serum albumin matrix with CA 19-9 antigen at specified levels



## Summary of Analytical Studies

**Imprecision:** Imprecision was tested for concentrations from approximately 17 to 1665 U/mL. The within run imprecision ranged from 1.7% CV to 6.4% CV. Between-run assay imprecision ranged from 2.4% CV to 5.7% CV. Total imprecision ranged from 3.0% CV to 8.9% CV.

**Analytical Sensitivity:** The lowest detectable level of CA 19-9 antigen distinguishable from zero (Access GI Monitor Calibrator S0) is 0.8 U/mL.

**Dilution Recovery (Linearity):** Linearity studies performed by diluting 6 human serum samples at various levels with Access GI Monitor S0 Calibrator provided an average recovery of 96%, with mean percent recoveries ranging from 93% to 100%.

**Methods Comparison:** A comparison of CA 19-9 antigen values from 405 samples, ranging from 0.0 to 236.0 U/mL, run with both the Access GI Monitor assay and the Fujirebio Diagnostics CA 19-9 RIA assay demonstrated acceptable agreement with the following statistical data:  $y = 0.9569x + 2.5726$ ,  $r = 0.9007$ .

**Sample Type Comparison:** A comparison of 80 matched serum and lithium heparin plasma samples, ranging from 0.0 to 1650.9 U/mL, using the Access GI Monitor assay gave the following statistical data using Deming calculations:  $y = 0.9842x - 0.5002$ ,  $r = 0.9995$ .

**Analytical Specificity:** There was no significant interference from therapeutic drugs or similar compounds in the Access GI Monitor assay. In addition, there was no significant interference from potential sample contaminants (bilirubin, hemoglobin, triglycerides, human serum albumin, and rheumatoid factor).

**Stability:** GI Monitor reagents are stable for 56 days after opening and calibrators are stable for 90 days after opening. The calibration curve is stable for 56 days.



## Summary of Clinical Studies

The 95<sup>th</sup> percentile (35 U/mL CA 19-9) for the apparently healthy subject population was set as the upper reference limit (URL) for the Access GI Monitor assay. The distribution of Access GI Monitor values for apparently healthy subjects and for subjects with various non-malignant and malignant conditions are consistent with results provided in the predicate device labeling.

Results from subjects who were diagnosed with pancreatic cancer and who were monitored over the course of disease demonstrate that CA 19-9 concentrations obtained with the Access GI Monitor assay paralleled results obtained with the predicate device.

Based on the pancreatic cancer monitoring subjects, the relative sensitivity and relative specificity, based on the respective URLs for the Access GI Monitor assay (URL = 35 U/mL) and the predicate device (URL = 37 U/mL), were 96.6% and 89.6%, respectively. The % agreement between the two assays was 95.1%.

## Conclusion

GI Monitor and GI Monitor Calibrators on the Access Immunoassay Systems is substantially equivalent to Fujirebio Diagnostics CA 19-9 RIA for the measurement of CA 19-9 antigen in human serum and plasma.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

DEC 29 2003

Mr. Brent Taber  
Senior Regulatory Specialist  
Beckman Coulter, Inc.  
1000 Lake Hazeltine Drive  
Chaska, MN 55318-1084

Re: k033038  
Trade/Device Name: GI Monitor and GI Monitor Calibrators on the Access  
Immunoassay Systems  
Regulation Number: 21 CFR 866.6010  
Regulation Name: Tumor associated antigen immunological test system  
Regulatory Class: Class II  
Product Code: NIG; JIT  
Dated: December 8, 2003  
Received: December 9, 2003

Dear Mr. Taber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

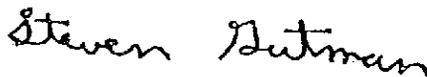
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.  
Director  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and  
Radiological Health

Enclosure

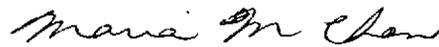
510(k) Number (if known): K033038Device Name: GI Monitor and GI Monitor Calibrators on the  
Access Immunoassay Systems**Indications For Use:**

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. This device is indicated for use in the measurement of CA 19-9 antigen to aid in the management of pancreatic cancer patients. The test is useful as an aid in monitoring of disease status in those patients having confirmed pancreatic cancer whose serum CA 19-9 antigen levels exceed 10 U/mL, the cut-off value for individuals who are Lewis blood group antigen negative. Serial testing for patient CA 19-9 antigen concentrations should be used in conjunction with other clinical methods used for monitoring pancreatic cancer.

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IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)




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 Division Sign-Off

**Office of In Vitro Diagnostic Device  
Evaluation and Safety**

OR

Over-The Counter Use \_\_\_\_\_

 Prescription Use  \_\_\_\_\_  
 (Per 21 CFR 801.109)
510(k) K033038

(Optional Format 1-2-96)