DEC 1 9 2003

BECKMAN COULTER

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: K033603

Submitter's Name and Address

Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318
Telephone: (952) 368-1383
Fax: (952) 368-7610
Contact: Valynda Machen

Date Prepared: November 14, 2003

Device Names

Proprietary Name: Intrinsic Factor Ab, Intrinsic Factor Ab Calibrators, and Intrinsic Factor Ab QC on the Access® Immunoassay Systems

Common Name: Immunoassay for the detection of intrinsic factor antibody

Classification Name: Vitamin B_{12} Test System

Predicate Device

DPC IFbAb

Diagnostic Products Corporation

5700 West 96th Street

Los Angeles, CA 90045-5597

510(k) Number: k811927

BECKMAN COULTER

Device Description

The Access Intrinsic Factor Ab reagents, calibrators, QC, and the Access Immunoassay Analyzers (Access, Access 2, Synchron LXi 725, and UniCel Dxl 800) comprise the Access Immunoassay Systems for the detection of intrinsic factor antibody in human serum and plasma.

Intended Use

The Access Intrinsic Factor Antibody assay is a paramagnetic particle, chemiluminescent immunoassay for the detection of intrinsic factor antibody in human serum and plasma using the Access Immunoassay Systems.

Comparison of Technological Characteristics

Attribute	DPC IFbAb RIA	Access IFAb
Intended Use	For the detection of intrinsic factor blocking antibody in serum.	For the detection of intrinsic factor antibody in human serum and plasma.
Assay Principles	DPC's IF bAb procedure detects anti-intrinsic factor blocking antibody in serum by its effect on the vitamin B12-binding capacity of the solid-phase intrinsic factor binder.	Utilizes the binding of intrinsic factor antibody to alkaline phosphatase enzyme conjugated to intrinsic factor, followed by a competitive binding reaction with monoclonal antibody coupled to the solid phase.
Solid Support	Microcrystalline cellulose particles	Paramagnetic particles
Detection System	Utilizes ^{57} Cobalt labeled vitamin B12; Measures bound radioactivity with a gamma counter	Utilizes dioxetane-based chemiluminescent substrate; Measures light production from a chemiluminescent reaction
Calibrator	Single level negative reference of liquid pooled human serum negative for intrinsic factor blocking antibody.	Single level calibrator of liquid synthetic matrix with an intrinsic factor antibody concentration of 1.00 AU/ml.

BECKMAN COULTER

Summary of Analytical Studies

Imprecision: Imprecision was tested for concentrations from approximately 1.1 to 14.2 AU/mL. The within run imprecision ranged from 1.3% CV to 1.5% CV. Between-run assay imprecision ranged from 4.4% CV to 5.1% CV. Total imprecision ranged from 4.6% CV to 5.3% CV.

Dilution Recovery (Linearity): Linearity studies performed by diluting serum patient samples at various levels with Access Intrinsic Factor Ab S0 Calibrator show that serial dilutions transform a positive sample result to a negative sample result.

Methods Comparison: A comparison of 127 values using the Access Intrinsic Factor Ab assay and a commercially available radioimmunoassay kit gave the following statistical data: Negative agreement=100%, Positive agreement =96.4%, and Overall Agreement = 92.1%.

Analytical Specificity: There was no significant interference from potential sample contaminants (bilirubin, hemoglobin, human serum albumin, and triglycerides). In addition, samples with vitamin B_{12} values of < 1500 do not interfere with the assay.

Stability: Intrinsic Factor Ab reagents, calibrators, and QC are stable for 56 days after opening. The calibration is stable for 14 days.

BECKMAN COULTER

Summary of Clinical Studies

Samples from an apparently healthy subject population were used to set the upper reference limit (URL) for the Access Intrinsic Factor Ab assay. A 99% non-parametric determination of results gave a URL value of 1.20 AU/mL.

The positive cutoff value was determined by Receiver Operator Curve (ROC) analysis of negative, equivocal, and positive samples. The positive cutoff was determined to be 1.53 AU/mL.

Patient samples (67 positive, 60 negative) from a clinical site were then used to measure agreement between the Access Intrinsic Factor Ab Assay and the predicate device.

The agreement between the two devices was calculated using an equivocal category. The negative agreement was 100%; the positive agreement was 96.4%; and the overall agreement was 92.1%.

Conclusion

Intrinsic Factor Ab, Intrinsic Factor Ab Calibrators, and Intrinsic Factor Ab QC on the Access Immunoassay Systems is substantially equivalent to DPC IFbAb RIA for the detection of intrinsic factor antibody in human serum and plasma.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 1 9 2003

Ms. Valynda Machen
Senior Regulatory Specialist
Beckman Coulter, Inc,
1000 Lake Hazeltine Drive
Chaska, MN 55318-1084

Re: k033603
Trade/Device Name: Intrinsic Factor Ab, Intrinsic Factor Ab Calibrators, and Intrinsic Factor Ab QC on the Access Immunoassay Systems
Regulation Number: 21 CFR 862.1810
Regulation Name: Vitamin B_{12} test system
Regulatory Class: Class II
Product Code: LIG; JJX, JIT
Dated: November 14, 2003
Received: November 17, 2003

Dear Ms. Machen:

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).

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 Gutman

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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K033603

Device Name: Intrinsic Factor Ab, Intrinsic Factor Ab Calibrators, and Intrinsic Factor Ab QC on the Access Immunoassay Systems

Indications For Use:

The Access Intrinsic Factor Ab assay is a paramagnetic particle, chemiluminescent immunoassay for the detection of intrinsic factor antibody in human serum and plasma using the Access Immunoassay Systems. It is intended for in vitro diagnostic use as an aid in the diagnosis of pernicious anemia.

(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol Benson for JeanCooper, DVM

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033603

Prescription Use X OR Over-The Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)