



May 3, 2024

Beckman Coulter, Inc.  
Kate Oelberg  
Senior Staff Quality and Regulatory Affairs  
1000 Lake Hazeltine Drive  
Chaska, Minnesota 55318

Re: K240800

Trade/Device Name: Access Intrinsic Factor Ab  
Regulation Number: 21 CFR 862.1810  
Regulation Name: Vitamin B12 test system  
Regulatory Class: Class II  
Product Code: LIG  
Dated: March 22, 2024  
Received: March 25, 2024

Dear Kate Oelberg:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Paula V. Caposino**  
-S

Paula Caposino, Ph.D.  
Deputy Director  
Division of Chemistry and Toxicology Devices  
OHT7: Office of In Vitro Diagnostics  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known)

K240800

Device Name

Access Intrinsic Factor Ab

Indications for Use (Describe)

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.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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## 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.

**510(k) Number K240800**

**Date Prepared:** May 2, 2024

**Submitted By:**

Beckman Coulter, Inc.  
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**Primary Contact:**

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### Device Name

**Common Name:** Access Intrinsic Factor Ab  
**Trade Name:** Access Intrinsic Factor Ab  
**Classification Name:** Radioassay, vitamin b12  
**Classification Code:** LIG  
**Classification Regulation:** 862.1810

### Predicate Device

**Device Name:** Access Intrinsic Factor Ab  
**510(k) Numbers:** K033603

### Device Description

The Access Intrinsic Factor Ab assay is a competitive binding immunoenzymatic assay. The Access assay consists of the reagent pack, calibrators and QCs. Other items needed to run the assay include substrate and wash buffer. The Access assay reagent pack, Access assay calibrators, Access QCs, along with the UniCel DxI Wash Buffer II are designed for use with the DxI 9000 Access Immunoassay Analyzer in a clinical laboratory setting.

## Intended 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.

## Comparison of Technological Characteristics to the Predicate

Parameter	Access Intrinsic Factor Ab on Access 2 Immunoassay System (Predicate)	Access Intrinsic Factor Ab on Dxl 9000 Access Immunoassay System
<b>Intended use</b>	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	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.
<b>Technology</b>	Two-step immunoenzymatic assay	Same
<b>Format</b>	Chemiluminescent	Same
<b>Calibration</b>	Single level calibrator of liquid synthetic matrix with an intrinsic factor antibody concentration of 1.0 AU/mL	Same
<b>Sample Type</b>	Serum and plasma	Same
<b>Results Interpretation</b>	<1.20 AU/mL Negative ≥ 1.20 to < 1.53 AU/mL Equivocal ≥1.53 AU/mL Positive	Same
<b>Instrument</b>	Access Immunoassay system	Dxl 9000 Access Immunoassay Analyzer
<b>Substrate</b>	Access Substrate	Lumi-Phos Pro Substrate

**Standard/Guidance Document Referenced (if applicable):**

CLSI EP05-A3: Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Third Edition

CLSI EP17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition

CLSI EP09c 3<sup>rd</sup> Edition: Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Third Edition

**Summary of Studies**

**Method Comparison:** A comparison of 128 serum samples using the Access Intrinsic Factor Ab assay on the Dxl 9000 Access Immunoassay Analyzer and Access 2 Immunoassay System gave the following statistical data using statistical analysis:

		Access 2		
		Negative	Equivocal	Positive
Dxl 9000	Negative	39	1	0
	Equivocal	0	7	2
	Positive	0	1	78
	Total	39	9	80
Negative Agreement		39 / 39 = 100%		
Positive Agreement		78 / 80 = 97.5%		
Total Agreement		(39 + 78 + 7) / 128 = 96.9%		

**Imprecision:** The assay was designed to have within-laboratory imprecision as listed below:

CV ≤ 10.0%

A study based on CLSI EP05-A3 performed on the Dxl 9000 Access Immunoassay Analyzer tested multiple samples in duplicate in 2 runs per day for a minimum of 20 days.

Concentration (AU/mL)			Repeatability (Within-run)		Between-run		Between-day		Within-Laboratory (Total)	
Sample	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Sample 1	80	1.0	0.03	2.7	0.02	1.8	0.03	2.6	0.04	4.2
Sample 2	80	1.3	0.03	2.0	0.02	1.8	0.04	3.3	0.06	4.3
Sample 3	80	1.5	0.04	2.4	0.00	0.0	0.05	3.1	0.06	3.9
Sample 4	80	1.6	0.03	1.7	0.06	3.7	0.02	1.5	0.07	4.4
Sample 5	80	3.4	0.06	1.9	0.08	2.5	0.07	1.9	0.12	3.7

Concentration (AU/mL)			Repeatability (Within-run)		Between-run		Between-day		Within-Laboratory (Total)	
Sample 6	80	14	0.2	1.7	0.2	1.3	0.4	2.6	0.5	3.3

**Other claims:** The claims for the analytical specificity, reference intervals, matrix comparison are unchanged and transferred from file K033603.

**Substantial Equivalence Comparison Conclusion**

Beckman Coulter's Access Intrinsic Factor Ab assay on the Dxl 9000 Access Immunoassay Analyzer is substantially equivalent to the Access Intrinsic Factor Ab assay on the Access 2 Immunoassay System as demonstrated through the information and data provided in this submission. The performance testing presented in this submission provides evidence that the device is safe and effective in its intended use.